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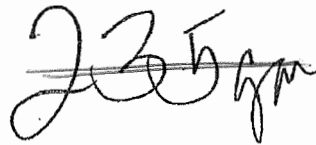
UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA**RICHARD W. WIEKING**
CLERK, U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIATAKEDA PHARMACEUTICAL CO., LTD.,
et al.,

Plaintiffs,

v.

TWI PHARMACEUTICALS, INC., et al.,
Defendant.

Case No. C-11-01609 JCS

Related Cases: C-11-0840 JCS,
C-11-01610 JCS**ORDER RE SUMMARY JUDGMENT
MOTIONS [Docket Nos. 160, 175 (redacted
publicly filed versions); 166, 204 (sealed
versions)]****[REDACTED VERSION]****FILED UNDER SEAL****I. INTRODUCTION**

Takeda Pharmaceutical Co., Ltd., Takeda Pharmaceuticals North America, Inc., Takeda Pharmaceuticals LLC, and Takeda Pharmaceuticals America, Inc. (hereinafter, referred to collectively as "Takeda") initiated this action under 35 U.S.C. § 271 and the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, in response to Defendants' Abbreviated New Drug Applications ("ANDA") No. 202-666, seeking approval from the Food and Drug Administration ("FDA") to manufacture and sell generic versions of Takeda's drug DEXILANT (dexlansoprazole).¹ Takeda alleges that TWi's ANDA products infringe two of its patents, U.S.

¹ Takeda alleged in its First Amended Complaint ("FAC") that the ANDA was submitted to the FDA by Defendant Anchen Pharmaceuticals, Inc. ("Anchen") and that ownership of the ANDA was transferred to TWi Pharmaceuticals, Inc. ("TWi") on May 10, 2011. FAC ¶¶ 33, 38. Anchen has been dismissed from this action, *see* Docket No. 103, but the parties agree that any references to Anchen's ANDA products apply with equal force to TWi because they refer to the same products. Hereinafter, the Court refers to the products in ANDA No. 202-666 as "TWi's ANDA products."

1 Patent No. 7,737,282 ("the '282 Patent") and U.S. Patent No. 7,790,755 ("the '755 Patent").²

2 TWi, in turn, asserts counterclaims seeking declaratory judgment that no valid claims of the '755
3 or '282 Patents are infringed.

4 Presently before the Court are the parties' cross-motions for summary judgment. Takeda
5 has filed a motion seeking summary judgment of infringement of the '282 Patent based on what it
6 contends is undisputed evidence that the 30-mg and 60-mg dextansoprazole drug products in
7 TWi's ANDA contain the amorphous form of dextansoprazole and therefore contain every
8 element of claims 1 and 2 of the '282 patent. *See* Motion for Summary Judgment of Infringement
9 of the '282 Patent ("Takeda SJ Motion (TWi)"). TWi brings a motion seeking summary judgment
10 that: 1) its ANDA products do not infringe the '755 Patent because Takeda cannot establish that
11 the composition of those products "begins to release" the active ingredient at a pH level of no less
12 than 5.0 and no more than 6.0, as is required under the asserted claims; 2) there is no subject
13 matter jurisdiction over claims IV and VII of Takeda's complaint to the extent they are based on
14 alleged infringement of the '282 Patent because the '282 Patent is not listed in the FDA Orange
15 Book and TWi has not filed a Paragraph IV certification with respect to it; 3) claims 1 and 2 of
16 the '282 Patent are invalid because they are anticipated by the Larsson³ and Barberich⁴
17 references; and 4) claims 1 and 2 of the '282 Patent are invalid as lacking the required written
18 description of the claimed dextansoprazole salts and compositions containing them.⁵ *See*
19 Defendant TWi Pharmaceuticals, Inc.'s Motion for Summary Judgment ("TWi SJ Motion").
20

21 ² Originally, Takeda alleged that TWi's ANDA products infringed six of its patents. Judgment of
22 non-infringement was entered as to four of these patents, *see* Docket No. 146, leaving only the
23 '282 and '755 Patents at issue.

24 ³ Larsson" refers to WO 96/02535 ("Larsson I") and U.S. Patent No. 5,948,789 ("Larsson II").
25 Local Rule 56-2 Stipulation of Undisputed Facts ("JSUF (TWi Motion)") ¶¶ 90-91. The parties
26 agree that there is no material difference between the disclosures of Larsson I and Larsson II.
27 JSUF (TWi Motion) ¶ 92.

28 ⁴ "Barberich" refers to WO 99/38513 ("Barberich I") and U.S. Patent App. No. 2003/0008903
("Barberich II"). The parties agree that there is no material difference between the disclosures of
Barberich I and Barberich II. JSUF ¶¶ 93-94 (TWi Motion).

⁵ TWi also incorporates and joins in "any invalidity summary judgment motion offered by any
defendant in any related case with respect to claims 1 and 2 of the '282 patent." TWi SJ Motion
at 15 n. 9.

Hearings on the motions were held on February 8, 2013 and February 22, 2013. For the reasons set forth below, Takeda's summary judgment motion is GRANTED. TWi's summary judgment motion is GRANTED in part and DENIED in part.⁶

II. BACKGROUND

A. The Accused Products

In its ANDA, TWi seeks approval from the FDA to market dextansoprazole delayed-release capsules in 30-mg and 60-mg dosage forms. JSUF (Takeda Motion) ¶¶ 5,16. TWi manufactures its ANDA products in Taiwan. *Id.* ¶ 13.

B. The Asserted Claims of the '282 Patent

Takeda alleges that TWi's ANDA products infringe claims 1 and 2 of the '282 Patent. Claim 1 of the '282 Patent claims an "amorphous compound of (R)-2-[[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl]methyl]sulfinyl]-1H-benzimidazole or a salt thereof." Joint Statement of Undisputed Facts for Takeda's Motion for Summary Judgment of Infringement of the '282 Patent ("JSUF (Takeda Motion)"), ¶ 1. The parties agree that the term "(R)-2-[[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl]methyl]sulfinyl]-1 H-benzimidazole" in the '282 Patent refers to dextansoprazole. *Id.* ¶ 4. Claim 2 of the '282 patent, which depends from claim 1, requires a "pharmaceutical composition comprising the amorphous compound according to claim 1 and a pharmaceutically acceptable excipient, carrier or diluent." *Id.* ¶ 2. The Court has construed the term "amorphous compound" in claims 1 and 2 of the '282 Patent to mean "a non-crystalline solid that lacks the long-range order characteristic of a crystal." *Id.* ¶ 3; Claim Construction Order at 71.

C. The Asserted Claims of the '755 Patent

Takeda alleges that TWi's ANDA products infringe claims 2 and 4 of the '755 Patent, each of which depends from claim 1. JSUF (TWi Motion) ¶ 1. Claim 1 describes a capsule comprising two compositions, one of which is "soluble in the pH range of 6.0 to 7.5" ("composition (i)") and another in which the drug is "released in the pH range of no less than 5.0

⁶ The parties have consented to the jurisdiction of a United States Magistrate Judge pursuant to 28 U.S.C. § 636(c).

1 to no more than 6.0” (“composition (ii)”). At the claim construction stage of the case, the Court
 2 was asked to construe the claim term specifying the range for composition (ii) (hereinafter, the
 3 “release term”). The primary dispute focused on whether the specified pH range refers to the
 4 threshold level at which release of the active ingredient begins, as Takeda asserted, or rather,
 5 represents the *only* pH values at which release or dissolution occurs. The Court adopted Takeda’s
 6 proposed construction, construing the claim term “released in the pH range of no less than 5.0 to
 7 no more than 6.0” to mean that the dexlansoprazole “begins to be released from the tablet, granule
 8 or fine granule at pH values within the range from 5.0 to 6.0.” Claim Construction Order at 70.
 9 In response to the argument that the claim term is indefinite because a person skilled in the art
 10 would not know what percentage of the drug needs to be released to satisfy the “begins to be
 11 released” requirement, the Court noted that “the phrase ‘begins to release’ is not a claim term but
 12 merely a proposed construction intended to convey the idea that the pH values in the term
 13 represent a threshold.” *Id.* at 67. The Court went on to find that the question of what amount of
 14 drug release satisfies this requirement does not render the claim term insolubly ambiguous to a
 15 person of ordinary skill in the art. *Id.*

16 **D. The Parties’ Contentions**

17 **1. Subject Matter Jurisdiction Over ‘282 Infringement Claim**

18 **a. TWi’s Motion**

19 TWi asserts there is no subject matter jurisdiction over Takeda’s ‘282 Patent infringement
 20 claim under 35 U.S.C. § 271(e)(2) because Takeda has not listed the ‘282 Patent in the “Orange
 21 Book” and TWi’s ANDA does not include a Paragraph IV certification. TWi SJ Motion at 14-15
 22 (citing *Eisai Co. v. Mutual Pharmaceutical Co., Inc.*, 2007 WL 4556958, at *6 (D.N.J. Dec. 20,
 23 2007); *Abbott Labs. v. Zenith Labs., Inc.*, 934 F.Supp. 925, 936 (N.D.Ill., 1995)). According to
 24 TWi, a Paragraph IV certification is a jurisdictional requirement under the Hatch-Waxman Act.⁷

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 26
 27 ⁷ In the Motion, TWi requests dismissal of both Count IV (asserted under the Hatch-Waxman
 28 Act) and Count VII of Takeda’s First Amended Complaint on this basis. Count VII, however, is
 asserted under § 271(a) and the Declaratory Judgment Act rather than the Hatch-Waxman Act.
 Therefore, this argument does not apply to Count VII.

1 **b. Takeda's Opposition**

2 Takeda rejects TWi's assertion that the Court lacks subject matter jurisdiction under §
3 271(e)(2) because the '282 Patent is not listed in the Orange Book. Takeda Opposition at 19-21.
4 According to Takeda, Supreme Court and Federal Circuit authority establish that it is the
5 submission of an ANDA, not a paragraph IV certification, that establishes jurisdiction in the
6 district courts for an act of infringement under § 271(e)(2). *Id.* at 19-20 (citing *Caraco*
7 *Pharmaceutical Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1680 n. 5 (2012); *AstraZeneca*
8 *Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1376-77 (Fed. Cir. 2012); *Glaxo Group Ltd. v.*
9 *Apotex, Inc.*, 376 F.3d 1339, 1343-44 (Fed. Cir. 2004); *Impax Labs., Inc. v. Aventis Pharms.*,
10 *Inc.*, 468 F.3d 1366, 1372-73 (Fed. Cir. 2006)). Takeda cites district court decisions that it
11 contends have reached the same conclusion. *Id.* at 12 (citing *Purdue Pharma Prods. L.P. v. Par*
12 *Pharm., Inc.*, 642 F. Supp. 2d 329, 363 n.49 (D. Del. 2009); *Cephalon, Inc. v. Sandoz, Inc.*, 2012
13 WL 682045, at *5 (D. Del. Mar. 1, 2012); *Teva Pharms. USA, Inc. v. Abbott Labs.*, 301 F. Supp.
14 2d 819, 829 (N.D. Ill. 2004); *Bayer Healthcare, LLC v. Norbrook Labs., Ltd.*, 2009 WL 6337911,
15 at *9 (E.D. Wis. Sept. 24, 2009)).

16 **c. TWi's Reply**

17 In its Reply brief, TWi asserts that Takeda has not cited any case in which a patentee was
18 able to maintain "an ANDA patent infringement action with respect to a patent that was never
19 listed in the Orange Book." TWi Reply at 12. According to TWi, *Eisai* is closely on point and in
20 that case, the court found that a Paragraph IV certification was required for subject matter
21 jurisdiction. *Id.* (citing 2007 WL 4556958, at *14 (D.N.J. Dec. 20, 2007)). TWi argues that the
22 cases cited by Takeda are "easily distinguished" on the grounds that in those cases: "(1) the
23 asserted patent was shortly thereafter listed in the Orange Book," *id.* at 12 n. 6 (citing *Cephalon,*
24 *Inc. v. Sandoz, Inc.*, 2012 WL 682045, at *4 (D. Del. Mar. 1, 2012)); "(2) changes in patent
25 certification from 'paragraph IV' to other certifications did not destroy already existing
26 jurisdiction over listed Orange Book patents," *id.* (citing *Caraco Pharm. Labs., Ltd. v. Novo*
27 *Nordisk A/S*, 132 S. Ct. 1670, 1680 (2012); *Bayer Healthcare LLC v. Norbrook Labs., Ltd.*, No.
28 08-cv-00953, 2009 WL 6337911, at *9 (E.D. Wis. Sept. 24, 2009)); and "(3) 'old-antibiotic' cases

1 that are expressly excluded from Orange Book listing requirements altogether provided
2 jurisdiction,” *id.* (citing *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1344 (Fed. Cir. 2004)).⁸

3 2. Infringement of the ‘282 Patent

4 a. Takeda’s Motion

5 Takeda asserts in its summary judgment motion that TWi’s ANDA products should be
6 found to infringe the ‘282 claims because TWi’s representations to the FDA and its admissions in
7 discovery establish that those products contain the claimed amorphous compound of
8 dexlansoprazole. Takeda SJ Motion (TWi) at 1. Takeda acknowledges that because the drug
9 products are manufactured in Taiwan, the fact that the dexlansoprazole used to manufacture them
10 is the solid amorphous form of dexlansoprazole does not establish infringement; rather, Takeda
11 must establish that the *finished* product that will be imported and sold into the United States will
12 contain amorphous dexlansoprazole in order to establish infringement. *Id.* at 6 (citing JSUF
13 (Takeda Motion) ¶ 6).

14 In support of its contention that TWi’s prior statements establish infringement of the ‘282
15 Patent, Takeda points first to the undisputed fact that TWi has informed the FDA that the active
16 pharmaceutical ingredient used in the manufacture of its ANDA products is the amorphous form
17 of dexlansoprazole. *Id.* at 2 (citing JSUF (Takeda Motion) ¶ 6). Takeda next cites the following
18 statement made by TWi to the FDA in the ANDA relating to its layering process⁹:

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20 ⁸ In its reply brief, TWi also cites *Eisai*’s holding that the plaintiff’s claim seeking a declaratory
21 judgment based on future infringement failed because the alleged future infringement depended
22 on two contingent future events, namely, FDA approval of the ANDA and the manufacturer’s
23 decision to market the generic drug pursuant to the ANDA. *Id.* at 12 (citing 2007 WL 4556958,
24 at *18). This argument goes to the question of whether Takeda can establish standing under the
25 Declaratory Judgment Act, an argument that should have been raised in TWi’s opening brief. As
26 TWi raised this issue for the first time in its reply brief, the Court declines to rule on it, as
27 discussed further below.

28 ⁹ In its brief, Takeda explains that TWi’s drug products, as described in the ANDA, are capsules
that contain multilayered “pellets,” which control the release of the active ingredient. *Id.* at 3
(citing Declaration of Allan S. Myerson, PhD, in Support of Takeda’s Motion for Summary
Judgment of Infringement of the ‘282 Patent (“Myerson Decl.”), Ex. 3 (Chen Dep. Ex. 40) at
ANC-DEXL0000437 & fig.)

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10 *Id.* at 4 (citing Myerson Decl., Ex. 8 (Chen Dep. Ex. 51) at ANC-DEXL0000779; JSUF (Takeda
11 Motion) ¶ 11). Takeda contends that this statement to the FDA indicates that TWi's ANDA
12 products do not crystallize during the manufacturing process and therefore this statement is
13 tantamount to an admission that the finished product contains the amorphous form of
14 dexlansoprazole. *Id.*

15 This conclusion finds further support, Takeda argues, in the deposition testimony of
16 TWi's 30(b)(6) witness, Dr. Shou-Chiung Chen, who is TWi's Vice President for Research and
17 Development, that [REDACTED]

18 [REDACTED] *Id.* at 4 (citing Myerson Decl., Ex. 7 (Jun. 20,
19 2012 Chen Dep. Tr. 118:1-10, 123:24-124:6-8); JSUF (Takeda Motion) ¶ 10). Takeda also cites
20 other statements made in this litigation that it contends are admissions that TWi's ANDA
21 products contain amorphous dexlansoprazole. First, Takeda points to TWi's interrogatory
22 responses stating that its "ANDA drug products do not contain a crystal or crystalline compound
23 of dexlansoprazole" *Id.* at 4 (citing Myerson Decl., Ex. 9 (TWi's Responses and Objections
24 to Plaintiffs First Set of Joint Interrogatories, July 28, 2011) at 17; JSUF (Takeda Motion) ¶ 14).
25 Takeda also relies on TWi's paragraph IV letter to Takeda, which states that "the ANDA drug
26 products do not include a crystal or crystalline compound of dexlansoprazole." *Id.* (citing
27
28 [REDACTED]

1 Myerson Decl., Ex. 10 at ANC-DEXL0000258; JSUF (Takeda Motion) ¶ 15). Based on this
2 evidence, Takeda's expert, Dr. Myerson, concluded that TWi's ANDA products contain
3 amorphous dextansoprazole. *Id.* at 5, 7 (citing Expert Report of Allan S. Myerson, PhD,
4 Regarding Infringement by TWi ("Myerson Report (TWi)" ¶¶ 22, 58-61). Dr. Myerson opines,
5 *inter alia*, that if TWi's drug product is not crystalline, as TWi has admitted in its interrogatory
6 responses and in its ANDA, "it must be the amorphous form of dextansoprazole." Myerson
7 Report ¶ 60. According to Takeda, because TWi has not offered any expert testimony to rebut the
8 opinion of Dr. Myerson, there is no genuine dispute of material fact and it is entitled to summary
9 judgment of infringement of the '282 Patent. *Id.* at 8.

10 **b. TWi's Opposition**

11 TWi argues that Takeda is not entitled to summary judgment of non-infringement because
12 it has not pointed to any final product testing that shows that the form of the dextansoprazole in
13 the ANDA products is amorphous. TWi Opposition at 1. TWi points out that at claim
14 construction, Takeda asked the Court to exclude dextansoprazole molecules such as those mixed
15 with solvents or air, from its construction of "an amorphous compound" and the Court agreed. *Id.*
16 at 3 (citing Claim Construction Order at 37, 39-40, 47). Thus, TWi contends, for the purposes of
17 this case, dextansoprazole exists in three forms: 1) a crystalline solid, characterized by a
18 molecular pattern over a long range; 2) an amorphous solid, which has no pattern over a long
19 range; and 3) "where the dextansoprazole molecules constitute neither a crystalline or an
20 amorphous solid, *i.e.*, other." *Id.* at 3-4. According to TWi, in order to prevail on its summary
21 judgment motion Takeda must offer evidence that establishes, as a matter of law, that the finished
22 product is the amorphous form and not one of the other two forms of dextansoprazole. *Id.* at 4.
23 TWi contends that Takeda has failed to meet this burden. *Id.*

24 TWi notes that Takeda has acknowledged that it is required to establish that the finished
25 product contains amorphous dextansoprazole and further points to testimony by Takeda's expert
26 conceding that he has not conducted any testing of TWi's ANDA products. *Id.* at 5-6. TWi
27 further cites statements made by Takeda in this litigation that dextansoprazole naturally tends to
28 convert to crystalline form. *Id.* at 7-9. In light of these statements and admissions by Takeda,

1 TWi asserts, summary judgment of infringement of the '282 Patent is not warranted. *Id.* at 9.
 2 TWi further argues that Takeda relies on the use of amorphous dextansoprazole to manufacture its
 3 ANDA products as evidence that the finished product contains amorphous dextansoprazole, but
 4 ~~that this evidence does not support Takeda's position because the new dextansoprazole is~~



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 9 TWi also contends that it has not made any admissions regarding whether the ANDA
 10 products contain amorphous dextansoprazole, arguing that in its notice letter to Takeda it only
 11 stated that Takeda would be "unable to carry its burden of proof to show that the proposed
 12 ANDA products contain the claimed 'crystalline compound' or a 'crystal' of dextansoprazole."
 13 *Id.* at 12. TWi also notes that its statements were made prior to the Court's claim construction
 14 and therefore do not constitute admissions that its ANDA products contain amorphous
 15 dextansoprazole as that term has been construed by the Court in this action. *Id.* at 12-13.

16 c. Takeda's Reply

17 In its Reply brief, Takeda reiterates its position that it has offered significant evidence of
 18 infringement, including TWi's statements to the FDA and in this litigation and expert testimony,
 19 even if it has not conducted its own testing. Takeda Reply at 3. Takeda rejects TWi's suggestion
 20 that the dextansoprazole in its ANDA products might take the form of "molecules in gases,
 21 solutions, and oils," asserting that there is no factual support for that position. *Id.* Takeda points
 22 out that in its Claim Construction order, the Court acknowledged that "typically amorphous
 23 materials used in oral pharmaceuticals are solids." *Id.* (citing Claim Construction Order at 48).
 24 Takeda further notes that at his deposition, TWi's expert was not able to name any orally-ingested
 25 non-solid amorphous materials used in pharmaceuticals. *Id.* (citing Takahashi Reply Decl., Ex. 2
 26 (Dec. 9, 2011 Rogers Dep. Tr.) at 58:3 - 59:3, 72:6-20). Further, Takeda contends, TWi's
 27 statements to the FDA acknowledge that the dextansoprazole in its ANDA products is in a solid
 28 form. *Id.* (citing Myerson Decl., Ex. 3 at ANC-DEXL0000438 (indicating that excipients used in

1 ANDA product fell below "limits for solid, oral dosage forms"); Myerson Decl., Ex. 8 at ANC-
2 DEXL0000769 (same); Takahashi Reply Decl., Ex. 3 (ANC-DEL0000796) (statement in ANDA
3 that a particular test was not performed on the ANDA product because it is "[n]ot applicable for
4 solid oral dosage forms").

5 Takeda also cites the testimony of its own expert, Dr. Myerson, that [REDACTED]

6 [REDACTED]
7 [REDACTED] *Id.* at 4 (citing
8 Mizerk Decl., Ex. A (Oct. 25, 2012 Myerson Dep. Tr.) at 116:16- 123:16 ("[W]e're forming a,
9 basically, a solid . . ."); *id.* ("[E]verything in there when this is done is a solid."). Dr. Myerson
10 also testified that solids must be either crystalline or amorphous, and Takeda contends that the
11 binary nature of solids is well-supported in the scientific literature. *Id.* (citing Decl. of Allan S.
12 Myerson, Ph.D., in Support of Takeda's Opening Claim Construction Brief ("Myerson Claim
13 Construction Decl.") ¶ 81 ("Solids can be crystalline or amorphous."), ¶ 23 ("Solids that are not
14 crystalline and have no long range order . . . are said to be amorphous."); Myerson Rep. ¶ 22
15 (same); Myerson Claim Construction Decl., Ex. 11 at DEX0014516 ("The terms amorphous and
16 non-crystalline are synonymous . . . and can be used interchangeably."); *id.*, Ex. 12 at
17 DEX0014612 ("[N]ot all solids are crystals. Materials that have short-range rather than long
18 range ordering . . . are non-crystalline solids. A noncrystalline solid is often referred to as an
19 amorphous solid."); *id.*, Ex. 13 at DEX0014769 ("A liquid may solidify in two ways: . . . to a
20 crystalline solid or . . . to an amorphous solid."); *id.*, Ex. 27 at DEX0014491 (defining
21 "[a]morphous [s]olid" as "[a] noncrystalline solid"); Expert Decl. of Robin D. Rogers in Support
22 of Handa Pharmaceuticals, LLC's Opening Markman Brief ("Rogers Claim Construction Decl."),
23 Ex. 3 at DEX0003649 ("Some authors [] sub-divide solids into crystalline and amorphous."); *id.*,
24 Ex. 4 at IPXL-0009902 (defining "amorphous" as "[n]oncrystalline . . ."); *id.*, Ex. 5 at IPXL-
25 0010285 (same); Takahashi Reply Decl., Ex. 2 (Dec. 9, 2011 Rogers Dep. Tr.) at 19:5-13;
26 Rogers Claim Construction Decl. ¶ 30 ("[T]he term 'amorphous' is an adjective that is
27 synonymous with 'noncrystalline.'"); *id.* ¶¶ 28-29).

1 Barberich references. *Id.* at 15. TWi points to the following undisputed facts to show that the
 2 claimed “amorphous compound” of dextansoprazole or salt thereof described in claim 1 of the
 3 ‘282 Patent is disclosed in Larsson: 1) Larsson discloses dextansoprazole, *id.* at 16 (citing JSUF
 4 (TWi Motion) ¶ 95); 2) Larsson discloses making salts with dextansoprazole, *id.* (citing JSUF
 5 (TWi Motion) ¶ 96; and 3) pharmaceutical salts of dextansoprazole prepared by “conventional
 6 processes” are claimed in claim 1 of Larsson II, U.S. Patent No. 5, 948,789, *id.* (citing JSUF (TWi
 7 Motion) ¶ 82). Further, these disclosures are presumed to be enabled, TWi asserts, because they
 8 are disclosed in a U.S. patent. *Id.* at 16 (citing *In re Antor Media Corp.*, 689 F.3d 1282, 1290
 9 (Fed. Cir. 2012) (“both claimed and unclaimed materials disclosed in a patent are presumptively
 10 enabling.”). With respect to the “pharmaceutical composition” limitation of claim 2, TWi points
 11 to the disclosure in Larsson of the use of dextansoprazole “in medicine.” *Id.* (citing Mizerk Decl.,
 12 Ex. 4 and 5).

13 As to Barberich, TWi cites to the following undisputed facts: 1) Barberich discloses
 14 dextansoprazole; 2) Barberich discloses making pharmaceutical salts with dextansoprazole; 3)
 15 Barberich discloses dextansoprazole as a “flowable powder”; 4) Barberich discloses specific
 16 examples of tablets and capsules, both of which are solid dosage forms, containing
 17 dextansoprazole. *Id.* (citing JSUF (TWi Motion) ¶¶ 97-99, 101). TWi further cites testimony by
 18 Takeda’s experts, Drs. Myerson and Atwood, in which they “specifically admit that even the oil
 19 from Larsson could be used to prepare a salt of dextansoprazole.” *Id.* at 16-17 (citing JSUF (TWi
 20 Motion) ¶ 83 (citing Mizerk Decl., Ex. 10 (Oct. 16, 2012 Atwood Dep. Tr.) at 255-56); Mizerk
 21 Decl., Ex. 12 (Oct. 25, 2012 Myerson Dep. Tr.) at 131). In fact, TWi asserts, there is no dispute
 22 that preparation of the salts described in claim 1 of the ‘282 Patent is not difficult using methods
 23 known in 1999, as inventor Keiji Kamiyama conceded. *Id.* at 17 (citing Mizerk Decl., Ex. 11
 24 (July 11, 2012 Kamiyama Dep. Tr.) at 153). Based on these undisputed facts, TWi contends that
 25 both Larsson and Barberich anticipate the asserted claims of the ‘282 Patent.

26 ii. Written Description

27 If Takeda takes the position that Larsson and Barberich do not disclose the salts claimed in
 28 claim 1 of the ‘282 Patent and their use with pharmaceutical excipients (described in claim 2),

1 Takeda rejects TWi's contention that the fact that the dextansoprazole used to
2 manufacture its ANDA products is amorphous has no bearing on the form of the dextansoprazole
3 in the finished product. *Id.* at 6. Rather, Takeda cites testimony by Dr. Myerson that

4 [REDACTED]
5 [REDACTED]
6 [REDACTED] *Id.* (citing Myerson Decl., Ex. 3 at ANC-DEXL0000458;

7 Myerson Report ¶ 58; JSUF (Takeda Motion) ¶ 12)

8 [REDACTED] *Id.* (citing Myerson Decl., Ex. 7
9 (Jun. 20, 2012 Chen Dep. Tr.) at 94:19-95:3; 118:1-10, 123:24-124:8).

10 Takeda argues that testing is not required to show infringement, contrary to TWi's
11 assertions, and that in the face of the evidence offered by Takeda, TWi has failed to produce
12 specific evidence demonstrating the existence of a genuine dispute of fact. *Id.* at 7-8 (citing
13 *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1372 (Fed. Cir. 2009)).

14 3. Validity of the '282 Patent

15 a. TWi Motion

16 TWi contends in its summary judgment motion that claims 1 and 2 of the '282 patent are
17 anticipated by Larsson¹⁰ and Barberich.¹¹ TWi SJ Motion at 15-17. In the alternative, TWi
18 argues, the asserted claims of the '282 Patent are invalid because they are not supported by
19 sufficient written description in the specification. *Id.* at 17-19.

20 i. Anticipation

21 According to TWi, even if there is a factual dispute about whether Larsson discloses pure
22 dextansoprazole as an amorphous solid, the undisputed facts establish that the dextansoprazole
23 "salts" and "compositions" claimed in the '282 patent are anticipated by both the Larsson and

24 ¹⁰ "Larsson" refers to WO 96/02535 ("Larsson I") and U.S. Patent No. 5,948,789 ("Larsson II").
25 Larsson I and II are attached as Exhibits 4 and 5, respectively, of the Mizerk Declaration. The
26 parties agree that there is no material difference between the disclosures of Larsson I and II.
27 JSUF (TWi Motion) ¶ 92.

28 ¹¹ Barberich" refers to WO 99/38513 ("Barberich I") and U.S. Patent App. No. 2003/0008903
("Barberich II"). Barberich I and II are attached as Exhibits 6 and 7, respectively, of the Mizerk
Declaration. The parties agree that there is no material difference between the disclosures of
Barberich I and II. JSUF (TWi Motion) ¶ 94.

1 TWi contends, it must implicitly concede that the '282 Patent does not contain adequate written
 2 description of these claimed features. *Id.* at 17-19. According to TWi, Takeda admits that there
 3 is no explicit description in the '282 Patent of the salts claimed in claim 1 or their use with any
 4 pharmaceutical excipients and that there is no way to know whether such salts, if made, would be
 5 amorphous or crystalline. *Id.* at 18 (citing JSUF (TWi Motion) ¶ 84 (citing Mizerk Decl., Ex. 10
 6 (Oct. 16, 2012 Atwood Dep. Tr.) at 347-349)). TWi also cites deposition testimony by the
 7 inventor, Keiji Kamiyama, that as far as he knew, no one at Takeda had actually made any salts of
 8 dextansoprazole before 1999 and that "no one at Takeda, including the inventors, even attempted
 9 to incorporate amorphous dextansoprazole in a pharmaceutical formulation." *Id.* (citing JSUF
 10 (TWi Motion) ¶87 (citing Mizerk Decl., Ex. 11 (July 11, 2012 Kamiyama Dep. Tr.) at 153-156)).
 11 *Id.* According to TWi, this evidence is sufficient to establish, as a matter of law, that the
 12 specification of the '282 Patent does not have sufficient written description to show that the
 13 inventors were in possession of the claimed invention. *Id.* at 18-19 (citing 35 U.S.C. § 112; *Ariad*
 14 *Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1344, 1351-1352 (Fed. Cir. 2010) (en banc);
 15 *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1348 (Fed. Cir. 2011); *Lockwood v.*
 16 *Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997); *Boston Scientific Corp. v. Johnson &*
 17 *Johnson*, 647 F.3d 1353, 1362-1364 (Fed. Cir. 2011)).

18 **b. Takeda's Opposition**

19 **i. Anticipation**

20 Takeda rejects TWi's anticipation theory, arguing that neither Larsson nor Barberich
 21 discloses dextansoprazole as an amorphous solid in salt form.¹² According to Takeda, TWi's
 22 position as to Larsson is based on the proposition that Larsson inherently discloses an amorphous
 23 salt of dextansoprazole because it expressly discloses the synthesis of an oil of dextansoprazole
 24 and "[t]he obtained products may thereafter be converted to pharmaceutically acceptable salts
 25 thereof by conventional processes." Takeda Opposition at 22 (citing JSUF (TWi Motion) ¶¶ 95-
 26 96; Mizerk Decl., Ex. 5 (Larsson II) at col.1, ll.14-17). Takeda does not dispute that at the

27
 28 ¹² Takeda does not challenge TWi's assertions that Larsson or Barberich disclose the
 "pharmaceutical composition" element of claim 2 of the '282 Patent.

1 priority date, a person of ordinary skill in the art would have been aware of conventional methods
2 for making salts. *Id.* Takeda argues that such a person would not, however, have known how to
3 make an amorphous salt of dextansoprazole that was a solid, as is required under the Court's
4 claim construction. *Id.* (citing Claim Construction Order at 71).

5 First, Takeda points out that TWi does not cite any expert testimony from Dr. Rogers,
6 TWi's expert on invalidity, that the salt made from the dextansoprazole oil disclosed in Larsson
7 would be a solid. *Id.* at 23. Takeda also cites the testimony of its own expert, Dr. Atwood, that
8 "[i]f one started with dextansoprazole as a solid and carried out the reaction, then one should end
9 up with a solid salt [but that] [i]f one started . . . with an oil, one might well end up with an ionic
10 liquid, an oil." *Id.* at 23 (quoting Purles Opposition Decl., Ex. 16 (Oct. 16, 2012 Atwood Dep. Tr.)
11 at 201:4-13). The testimony of Dr. Kamiyama that TWi cites -- that it was easy to prepare an
12 amorphous salt of dextansoprazole that is solid -- is not relevant, Takeda contends, because Dr.
13 Kamiyama was testifying about the synthesis of amorphous salts conducted in 2000, after the
14 priority date of the '282 Patent; moreover, Takeda argues, the only evidence in the record is that
15 in the experiments Dr. Kamiyama was describing, he used solid forms of dextansoprazole as
16 starting materials rather than an oil. *Id.* (citing Purles Opposition Decl., Ex. 17 (July 11, 2012
17 Kamiyama Dep. Tr.) at 151:11-152:14; *id.*, Ex. 18 (Dep. Ex. 700 (U.S. Patent No. 7,271,182,
18 assigned to Drs. Kamiyama and Hashimoto), at Reference Example 1 and Examples 4 and 5
19 (describing synthesis of amorphous salts from crystalline dextansoprazole)). Because TWi has not
20 produced any evidence that shows that the salt made from the oil disclosed in Larsson would
21 necessarily be a solid, Takeda argues, TWi has not established by clear and convincing evidence
22 that Larsson inherently anticipates claim 1 of the '282 Patent. *Id.* at 24.

23 Second, Takeda argues that Barberich also does not anticipate the asserted claims because
24 it does not disclose the synthesis of any solid form of dextansoprazole, but merely incorporates by
25 reference the synthesis methods disclosed in prior art such as Larsson. Because Larsson also does
26 not disclose the synthesis of a solid form of dextansoprazole as a salt, Barberich is not enabled,
27 Takeda contends. *Id.* at 23-24 (citing Atwood Report ¶ 70-71, 100-106; *Amgen Inc. v. Hoechst*
28 *Marion Roussel, Inc.*, 314 F.3d 1313, 1354 (Fed. Cir. 2003)).

1 Finally, Takeda argues that TWi's "dexlansoprazole salt" theory should not be considered
2 because it was not raised during discovery and therefore is in violation of Patent Local Rule 3-3.
3 *Id.* at 22-23 (citing Patent L.R. 3-3(a), (c); Purles Opposition Decl., Ex. 15 (Invalidity
4 Contentions) at 66; *02 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355 (Fed. Cir.
5 2006)).

6 **ii. Written Description**

7 Takeda argues that claims 1 and 2 of the '282 patent are not invalid for lack of adequate
8 written description. *Id.* at 24. Takeda does not dispute that there is no explicit description in the
9 '282 Patent of the amorphous salt of claim 1 or its use in a pharmaceutical composition but
10 contends that the written description requirement is satisfied because the '282 Patent discloses the
11 synthesis of an amorphous solid of dexlansoprazole and describes specific examples of salts of
12 dexlansoprazole. *Id.* According to Takeda, this disclosure "in combination with conventional
13 processes that TWi admits were in the prior art," would be sufficient to describe an amorphous
14 solid salt of dexlansoprazole to a person of ordinary skill in the art. *Id.* (citing '282 Patent, col.1,
15 l. 65 - col. 2, l. 2; col. 2, ll. 3-10; Atwood Report ¶ 121)).

16 Takeda argues that actual reduction to practice is not required to satisfy the written
17 description requirement, so long as one of skill in the art can "visualize or recognize" the claimed
18 invention based on the disclosure in the specification. *Id.* (citing *Centocor Ortho Biotech, Inc. v.*
19 *Abbott Labs.*, 636 F.3d 1341, 1353 (Fed. Cir. 2011); *Volterra Semiconductor Corp. v. Primarion,*
20 *Inc.*, 796 F. Supp. 2d 1025, 1064 (N.D. Cal. 2011)). Takeda points to the testimony of Drs.
21 Atwood and Kamiyama, which Takeda contends supports the conclusion that the '282 Patent
22 contains adequate written description of a solid salt of dexlansoprazole. *Id.* at 25 (citing Purles
23 Opposition Decl., Ex. 16 (Oct. 16, 2012 Atwood Dep. Tr.) at 201:4-13 (testifying that "[i]f one
24 started with dexlansoprazole as a solid and carried out the reaction, then one should end up with a
25 solid salt."); *id.*, Ex. 17 (July 11, 2012 Kamiyama Dep. Tr.) at 153:5-22 (testifying that it was
26 "not that difficult" to prepare an amorphous solid salt of dexlansoprazole from an amorphous
27 solid compound of dexlansoprazole). Moreover, Takeda asserts, the person of ordinary skill in
28 the art in 1999 would have understood the inventors of the '282 Patent had possession of a

1 pharmaceutical composition of an amorphous solid salt of dexlansoprazole in light of the fact that
 2 such a person would have understood from prior art such as Barberich how to make a solid
 3 dosage form of dexlansoprazole. *Id.* (citing Mizerk Decl., Ex. 7 (Barberich II) at 4 (Example 2);
 4 Atwood Report ¶ 122; Purles Opposition Decl., Ex. 19 (Nov. 9, 2012 Rogers Dep. Tr.) at 65:9-16
 5 (admitting that the teachings of Larsson could be used to make a pharmaceutical composition)).
 6 Thus, Takeda asserts, the evidence at a minimum creates a factual dispute as to whether one
 7 skilled in the art would have understood Takeda's invention to encompass salts of the amorphous
 8 solid of dexlansoprazole, precluding summary judgment of invalidity for lack of adequate written
 9 description.

10 **c. TWi Reply**

11 **i. Anticipation**

12 TWi asserts that Takeda has conceded that both Larsson and Barberich disclose
 13 amorphous and crystalline salts of dexlansoprazole, thus supporting entry of summary judgment
 14 of anticipation. TWi Reply at 14. TWi rejects Takeda's reliance on the testimony of its expert,
 15 Dr. Atwood, that a salt of dexlansoprazole made using conventional processes "might or might
 16 not" be a solid, pointing to testimony by Dr. Atwood in which he stated that "typically one would
 17 expect the salt to be a solid." *Id.* (citing JSUF (TWi Motion) ¶ 82). TWi further contends that
 18 whether one starts with a solid or an oil is irrelevant as Takeda admits that the first step of
 19 preparing a salt is dissolving the dexlansoprazole in a solvent. *Id.* (citing JSUF (TWi Motion) ¶¶
 20 87-89). According to TWi, "[g]iven that Dr. Atwood testified that [the] expectation is that the salt
 21 would be a solid, Takeda has not rebutted the presumption that the Larsson and Barberich
 22 references disclose the claimed solid dexlansoprazole salts." *Id.* (citing *In re Antor Media Corp.*,
 23 689 F.3d 1282, 1288 (Fed. Cir. 2012)). Because Takeda has failed to come forward with
 24 evidence that the disclosures of Larsson and Barberich are not enabled, TWi argues, this prior art
 25 anticipates claim 1. *Id.* Further, TWi asserts, Takeda did not address in its Opposition brief
 26 TWi's argument that Larsson and Barberich disclose the "pharmaceutical composition" required
 27 under claim 2 of the '282 Patent. *Id.*
 28

1 **ii. Written Description**

2 TWi argues that Takeda's assertion that dexlansoprazole subjected to conventional
3 processes is sufficient disclosure to meet the written description argument is inconsistent with its
4 position as to anticipation. *Id.* According to TWi, "Takeda cannot have it both ways." *Id.* To
5 the extent Takeda argues that Larsson and Barberich do not disclose the claimed salts, the written
6 description in the '282 Patent is insufficient, TWi asserts. *Id.*

7 **4. Infringement of the '755 Patent**

8 **a. TWi Motion**

9 TWi contends that it is entitled to summary judgment of non-infringement of the '755
10 Patent because Takeda has not demonstrated a genuine issue of material fact regarding whether
11 "composition (ii)" of TWi's ANDA products "beings to release" the active ingredient at a pH
12 level of 5.0. TWi SJ Motion at 2. In support of this position, TWi makes the following
13 arguments: 1) Takeda has offered evidence based on tests of expired product and therefore, this
14 evidence is inadmissible under *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311 (9th Cir.
15 1995); 2) Takeda's expert testimony based on these tests is inadmissible under *Daubert* because
16 the tests were "created solely for this litigation and ignored other testing showing contrary
17 results;" and 3) even if they are considered, the test results upon which Takeda relies show that
18 TWi's ANDA products begins to release active ingredient at pH less than 5.0 and therefore do not
19 infringe under the Court's claim construction. *Id.*

20 Regarding the use of expired product, TWi relies on undisputed facts, namely, that: 1) the
21 drug samples used in the Advantar tests that were the basis for Dr. Charman's expert report were
22 manufactured on May 21, 2010; 2) the tests were conducted after Advantar received the samples
23 of TWi's ANDA products, on June 29, 2012; and 3) [REDACTED]
24 [REDACTED] *Id.* at 4 (citing JSUF (TWi), ¶¶ 28-31; Mizerk Decl., Ex. 1 at ¶ 46). TWi contends
25 that under these circumstances, Dr. Charman's conclusions are not sufficiently tied to the facts of
26 the case to satisfy *Daubert* because FDA regulations do not permit the sale of expired product and
27 therefore, the expired product is not the one that will infringe if the ANDA is approved. *Id.* at 5
28 (citing *Poosh v. Philip Morris USA, Inc.*, 2012 WL 5199450, at *2 (N.D. Cal. Oct. 22, 2012); *In*

1 *re Brimonidine Patent Litig.*, 643 F.3d 1366, 1377 (Fed. Cir. 2011)). According to TWi, under
2 similar circumstances, courts have found that opinions based on results obtained from testing
3 expired product are not admissible. *Id.* (citing *SmithKline Beecham Corp. v. Apotex Corp.*, 2002
4 WL 1613724, at *2 (N.D. Ill. 2002); *Apotex, Inc. v. Cephalon, Inc.*, 2012 WL 1080148 (E.D. Pa.
5 Mar. 28, 2012)).

6 TWi also argues that Dr. Charman's opinions should be found unreliable under *Daubert*
7 because they were based solely on tests conducted for this litigation and ignored results obtained
8 by Advantar in tests that were conducted for Takeda's counsel before Dr. Charman was retained.
9 *Id.* at 5-10.¹³ According to TWi, at the claim construction stage of the case, Dr. Charman could
10 not state what testing methodology should be used to determine whether his definition of the
11 release claim term was met and could not say how much release would be required to find that a
12 drug product begins to be released at the 5.0 pH threshold. *Id.* (citing Docket No. 59, Ex. 2
13 (Charman Dep.) at 112:8-113:1, 122:21-123:5). It was only after Dr. Charman reviewed the test
14 results in Advantar's June 29, 2012 report, which were obtained using a testing protocol
15 developed by Advantar based on its prior testing and recommended to Dr. Charman by Advantar,
16 that Dr. Charman concluded that the "begins to release" requirement means release of more than
17 10% of the total drug in the product after two hours. *Id.* at 7. According to TWi, Dr. Charman's
18 reliance on Advantar's testing protocol indicates that the methodology is not scientifically
19 acceptable. *Id.* at 9.

20 TWi further contends that Dr. Charman's methodology is inconsistent with Takeda's
21 position at the claim construction stage of the case, when Takeda argued that a person of ordinary
22 skill in the art would know how to test to assess whether the release term is met based on the
23 prosecution history. *Id.* at 9-10. According to TWi, the test referenced by Takeda was not used
24 by Dr. Charman. *Id.* at 10. TWi further asserts that in Takeda's '755 Patent contentions, Takeda
25 referenced in vitro release profiles to show that its Dexilant product was covered by the '755
26
27

28 ¹³ The undisputed facts relating to the earlier Advantar testing, including the results of that testing,
are set forth in JSUF (TWi Motion) ¶¶ 33-62.

1 Patent, referencing tests that differed from those conducted by Dr. Charman. *Id.* (citing JSUF
2 (TWi Motion) ¶¶ 79, 81).

3 TWi also argues that under the “proper claim construction,” there is no material dispute
4 that TWi’s ANDA products begin to release active ingredient at a pH level below 5.0. *Id.* (citing
5 *JSUF* (TWi Motion) ¶¶ 43-70). [REDACTED]

6 [REDACTED]
7 [REDACTED]
8 *Id.* (citing *JSUF* (TWi Motion) ¶ 66). [REDACTED]
9 [REDACTED]
10 [REDACTED]

11 *Id.* at 10-1 (citing *JSUF* (TWi Motion) ¶ 66). TWi
12 asserts that these amounts are particularly significant because [REDACTED] of the total active
13 ingredient in TWi’s ANDA products is contained in the granules alleged to constitute the
14 “composition (ii)” granules. *Id.* at 11 (citing *JSUF* (TWi Motion) ¶ 25).

15 According to TWi, Dr. Charman’s “10%/two-hour time point is completely arbitrary, and
16 in the case of TWi, appears to have been selected because significant release begins at the two-
17 hour time point and even greater release occurs before the 2 1/2 hour time point is reached under
18 Dr. Charman’s testing.” *Id.* (citing *JSUF* (TWi Motion) ¶¶ 43-70). TWi further contends that the
19 ‘755 Patent specification indicates that release should be measured over at least 5 hours. *Id.*
20 (citing ‘755 Patent, col. 10, ll. 13-17) (“The rate of elution of active ingredient from the active
21 ingredient release-controlled tablet, granule or fine granule thus obtained is desirably 10% or less
22 for 5 hours in a solution of pH 6.0, and 5% or less for one hour and 60% or more for 8 hours in a
23 solution of pH 6.8”). In addition, according to TWi, during patent prosecution, the inventor
24 testified that at a pH level of 6.8, the “composition (i)” disclosed in the ‘755 Patent, which was
25 designed to release at pH 6.75, the granule “begins to release” after about 3.5 hours. *Id.* (citing
26 *JSUF* (TWi Motion) ¶ 74 (citing testimony of Takashi Kurasawa)). TWi contends that this
27 testimony contradicts Dr. Charman’s position that release should be measured at two hours. *Id.*
28 TWi also notes that in its interrogatory responses, Takeda cited testing of its own Dexilant

1 product to show that it began to release between pH levels 6.5 and 7.0 even though it took more
2 than two hours to release 10 % of the API. *Id.* (citing JSUF (TWi Motion) ¶ 80).

3 TWi also argues that Takeda's position amounts to a request for a new claim construction
4 which should be rejected as untimely. *Id.* at 12. Further, it asserts, if this new construction of the
5 release term is adopted, the claim is invalid because the question of how much API must be
6 released to meet the "begins to release requirement" is insolubly ambiguous to a person skilled in
7 the art. *Id.* at 12-13.

8 **b. Takeda Opposition**

9 Takeda does not dispute that the Advantar test results show some measurable release of
10 dexlansoprazole at pH levels below 5.0. It contends, however, that the small amount of
11 dexlansoprazole that is released at pH levels below 5.0 is not sufficient to place the ANDA
12 products outside the scope of the claim and further, that this is a factual issues that can only be
13 resolved at trial. Takeda Opposition at 2. Takeda notes that the Court explicitly declined to
14 specify at the claim construction stage of the case what type of testing would be required to
15 determine whether the release term was satisfied, leaving this question to be addressed at trial
16 through expert testimony. *Id.* at 3-4. This approach is consistent with Federal Circuit precedent,
17 Takeda asserts, pointing to cases holding that courts need not eliminate all ambiguity in
18 construing claim terms but rather, should only define terms to the level of specificity that is
19 warranted by the language of the claim and the evidence. *Id.* at 4 (citing *Acumed LLC v. Strkyer*
20 *Corp.*, 483 F.3d 800 (Fed. Cir. 2007); *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351 (Fed.
21 *Cir.* 1998); *Biotec Biologische Naturverpackungen GmbH & Co. v. Biocorp, Inc.*, 249 F.3d 1341
22 (Fed. Cir. 2001); *Modine Mfg. Co. v. Int'l Trade Comm'n*, 75 F.3d 1545 (Fed. Cir. 1996)).
23 According to Takeda, "where 'the claim language does not require a particular form of testing,
24 this inquiry is not a claim construction question' but is 'review[ed] . . . as a question of fact.'" *Id.*
25 at 5 (quoting *Union Carbide Chems. and Plastics Tech. Corp. v. Shell Oil Co.*, 425 F.3d 1366,
26 1377 (Fed. Cir. 2005), overruled on other grounds by *Cardiac Pacemakers, Inc. v. St. Jude Med.,*
27 *Inc.*, 576 F.3d 1348 (Fed. Cir. 2009)).
28

1 Takeda argues further that there is a genuine dispute of material fact as to the testing
2 criteria that should be used to decide whether TWI's ANDA products meet the release limitation
3 and that substantial evidence supports Dr. Charman's approach. *Id.* Takeda points to the
4 following evidence in support of Dr. Charman's approach:

- 5 • the monograph on dissolution testing in the United States Pharmacopeia ("USP"), which
6 recognizes that for delayed-release dosage forms, a product passes a dissolution test if no
7 individual dosage unit shows more than 10% dissolution in acid medium. *Id.* at 6 (citing
8 Charman Decl., Ex. B.21 (2012 USP section on dissolution) at 301, Acceptance Table 3;
9 Takahashi Decl., Ex. F (1995 USP section on dissolution) at 1796, Acceptance Table 2
10 (same)).
- 11 • the USP section on delayed release lansoprazole (which is an enantiomer of
12 dexlansoprazole), which "permits dissolution of less than 10% in the acid stage in a two-
13 stage experiment designed to simulate passage through an acidic stomach (in the first
14 stage) followed by simulated intestinal dissolution (in the second stage)." *Id.* (citing
15 Takahashi Decl., Ex. G (2009 USP section on lansoprazole delayed-release capsules) at
16 2753 (stating as to acid stage "[t]olerances" that "[n]ot more than 10% of the labeled
17 amount of [lansoprazole] is dissolved in 60 minutes")).
- 18 • the FDA's Dissolution Methods Database entry for dexlansoprazole, recommending that
19 in testing dexlansoprazole dissolution, sampling for the acid stage should be conducted at
20 120 minutes. *Id.* at 7 (citing Takahashi Decl., Ex. P (Dissolution Methods)).
- 21 • testimony by Impax's expert, Dr. Augsburger, that once the delayed release product
22 reaches its target pH, the release should be "relatively rapid." *Id.* (citing Purles Decl., Ex.
23 6 (Nov. 6, 2012 Augsburger Dep. Tr.) at 116:6-18).
- 24 • the statement in the '755 Patent specification noting that "the usual enteric coat" dissolves
25 "rapidly." *Id.* (citing '755 Patent, col. 6, l. 66 - col. 7, l. 12).
- 26 • Dr. Charman's deposition testimony that "any meaningful test for infringement must have
27 an amount limitation to account for small amounts of dissolution that inevitably occur in
28 any in vitro dissolution test of any significant duration," especially in light of

1 manufacturing defects that commonly result in inappropriately coated or uncoated drug in
2 the formulation. *Id.* (citing Purles Decl., Ex. 7 (Nov. 1, 2012 Chairman Dep. Tr.) at 58:16-
3 59:8).

4 Takeda argues that TWi's reliance on the '755 Patent specification and prosecution history is
5 misplaced. *Id.* at 8. As to TWi's reliance on col. 10, ll. 13-17 of the '755 Patent, stating that
6 "[t]he rate of elution of active ingredient from the active ingredient release-controlled tablet,
7 granule or fine granule thus obtained is desirably 10% or less for 5 hours in a solution of pH 6.0,
8 and 5% or less for one hour and 60% or more for 8 hours in a solution of pH 6.8," Takeda
9 contends that the specification makes clear that the threshold pH for this formulation was "6.75 or
10 above." *Id.* (citing '755 Patent, col. 10, l.2). In other words, according to Takeda, "rapid and
11 significant" release for this particular embodiment would only be expected at a pH of 6.75 or
12 higher." *Id.* Takeda reasons, "[t]hat release was relatively slow and minimal at pH 6.0, a pH
13 level significantly below the target pH of this particular embodiment, is in no way inconsistent
14 with Dr. Charman's opinion that the claimed formulation should show rapid and significant
15 dissolution above its target pH." *Id.* Takeda asserts that it has shown as to TWi's formulation
16 significant and rapid release of dexlansoprazole at target pH levels of 5.9 and 7.4, which falls
17 within the scope of the '755 claims. *Id.*

18 Takeda also rejects TWi's contention that the dissolution testing of Dr. Kurasawa cited by
19 the applicants during patent prosecution contradicts Dr. Charman's position. *Id.* According to
20 Takeda, Dr. Kurasawa's test was conducted at pH 6.8, a pH level "much lower than the pH 7.5
21 upper end of the pH range for the high-pH granule described in claim 1." *Id.* Thus, it contends,
22 "[t]hat the granule released drug slowly at pH level of 6.8 does not indicate how rapidly the drug
23 would release within two hours at the higher pH of 7.5, and thus in no way undermines Dr.
24 Charman's opinion." *Id.*

25 Takeda argues that TWi's reliance on its interrogatory responses regarding statements in
26 its New Drug Application ("NDA") addressing whether Dexilant was covered by the '755 patent -
27 - which described testing of its own product -- is also misplaced. *Id.* at 8-9. Takeda does not
28 dispute that different tests were used but argues that the test described in the interrogatory

1 response was “merely intended to show that the behavior of the Dexilant granules as reflected in
2 the NDA tests was consistent with the limitations of the ’755 patent: the low-pH granules in
3 Dexilant dissolved and completely released drug at pH 6.0 within two hours, and the high-pH
4 granules dissolved and completely released drug within 2 hours at pH levels of 7.0, 7.2, and 7.5.”
5 *Id.* at 9 (citing Purles Decl., Ex. 9 (NDA Excerpt) at DEX0011277-82; Charman Decl. ¶ 27).
6 According to Takeda, the NDA experiments were designed to show complete release of drug
7 rather than to test for infringement and therefore were not designed to determine the pH level at
8 which release begins. *Id.* (citing Charman Decl. ¶ 27).

9 Takeda also rejects TWi’s contention that Dr. Charman’s opinions do not satisfy the
10 requirements of Rule 702 of the Federal Rules of Evidence and *Daubert*. *Id.* According to
11 Takeda, there is no “off-the-shelf” dissolution test for determining whether drug release *does not*
12 occur below a given pH; rather, dissolution testing is typically used to establish the amount of
13 dissolution that occurs at a particular pH. *Id.* (citing Charman Decl. ¶ 8). Therefore, it asserts,
14 Advantar was required to design a customized dissolution test. *Id.* The fact that the test was
15 developed for this litigation, however, does not render the test inadmissible, Takeda argues. *Id.* at
16 10-11. Rather, according to Takeda, expert testimony prepared for litigation is admissible if “the
17 experts . . . explain precisely how they went about reaching their conclusions and point to some
18 objective source -- a learned treatise, the policy statement of a professional association, a
19 published article in a reputable scientific journal or the like -- to show that they have followed the
20 scientific evidence method, as it is practiced by (at least) a recognized minority of scientists in
21 their field.” *Id.* at 11 (quoting *Clausen v. M/V New Carissa*, 339 F.3d 1049, 1056 (9th Cir.
22 2003)).

23 Here, Takeda asserts, Dr. Charman has developed a test that is supported by scientific
24 principles and objective sources. *Id.* at 11-12 (citing Charman Report ¶¶ 58-81; Charman Decl.
25 Exs. B.3, B.4 and B.5 (Advantar reports)). Takeda argues that TWi has not identified any specific
26 ways in which Dr. Charman’s testing fails to adhere to scientific method or lacks objective
27 support and its assertion that Takeda manipulated the prior test results by modifying the protocol
28 to omit the use of the surfactant sodium dodecyl sulfate (“SDS”) or use a two-stage test are

1 unfounded. *Id.* at 12. Takeda contends that Dr. Charman's decision not to use SDS in the tests
2 upon which he based his report, even though SDS had been used in the earlier tests conducted by
3 Advantar, was based on Advantar's conclusion that the SDS was causing the enteric coating of
4 the low pH granules to disintegrate below the target pH level. *Id.* at 12-13 (citing Charman Decl.
5 ¶¶ 19-22; Takahashi Decl., Ex. J (May 9 Report) at DEX1672037). Takeda points out that TWi
6 also conducted dissolution testing of dextansoprazole granules without using SDS. *Id.* at 13
7 (citing Purles Decl., Ex. 20 (Dep. Ex. 110) at ANC-DEXL0006471 (setting forth a protocol for
8 dissolution testing that does not include SDS); *id.*, Ex. 10 (Nov. 8, 2012 Gray Dep. Tr.) at 31:17-
9 32:3, 57:19-59:20). Furthermore, Takeda asserts, Dr. Charman testified that he never
10 contemplated including the use of SDS in Advantar's testing protocol for dissolution testing of
11 dextansoprazole. *Id.* (citing Purles Decl. Ex. 7 (Nov. 1, 2012 Charman Dep. Tr.) at 109:22-
12 112:24; *id.* Ex. 1 (Oct. 31, 2012 Charman Dep. Tr.) at 196:2-198:2).

13 Takeda also argues that a February 7, 2012 email from Takeda's counsel asking Advantar
14 if SDS should be used in the dissolution medium and whether a two-stage test should be used
15 does not support TWi's assertion that Takeda acted improperly. *Id.* at 13 (citing Mizerk Decl.,
16 Ex. 1-R at DEX1678010 (Feb. 7, 2012 email). According to Takeda, these questions do not show
17 any improper conduct on its part given that TWi has conducted dissolution tests that do not use
18 SDS and a two-stage approach is provided for in the USP. *Id.* (citing Purles Decl., Ex. 11 (Jun.
19 20, 2012 Chen Dep. Tr.) at 186:9-19 (testimony from TWi's 30(b)(6) witness that "for the R&D
20 experiment, we don't use any SDS in the medium")). Takeda also notes that Dr. Charman made
21 several changes to the Advantar testing protocols, further undermining TWi's position. *Id.* (citing
22 Charman Report ¶ 60). According to Takeda, the prior testing by Advantar has no bearing on the
23 admissibility of Dr. Charman's tests and at most goes to the weight of the evidence. *Id.* at 14
24 (citing *Kennedy v. Collagen Corp.*, 161 F.3d 1226, 1231 (9th Cir. 1998)). Takeda also cites
25 testimony of the experts of the other Defendants in the related cases that they found Dr.
26 Charman's testing to be "reasonable," even though they believed SDS should be included in the
27 dissolution medium. *Id.* (citing Purles Decl., Ex. 5 (Nov. 14, 2012 Amiji Dep. Tr.) at 110:24-
28 111:19; *id.*, Ex. 6 (Nov. 6, 2012 Augsburg Dep. Tr.) at 49:19-50:19, 51:9-52:4). In addition, to

1 the extent TWi challenges Dr. Charman's interpretation of the test results, Takeda argues, this is a
 2 question that goes to the weight of the evidence, not its admissibility. *Id.* at 15 (*Gutierrez v.*
 3 *Johnson & Johnson*, 2006 WL 3246605, at *8 (D.N.J. Nov. 6, 2006); *Tristrata Tech., Inc. v. Mary*
 4 *Kay, Inc.*, 423 F. Supp. 2d 456, 463–64 (D. Del. 2006); *In re Diet Drugs Prods. Liab. Litig.*, 2000
 5 WL 962545, at * 13 (E.D. Pa. June 28, 2000)).

6 Takeda rejects TWi's assertion that Dr. Charman's results are inadmissible because
 7 expired product was used by Advantar. *Id.* at 16. According to Takeda, "there is 'no reason to
 8 assume that on the date a product is no longer within the FDA-required shelf life for the purposes
 9 of commercialization, it also ceases to be structurally representative of the product.'" *Id.* at 16
 10 (quoting *In re Omeprazole Patent Litig.*, 490 F. Supp. 2d 381, 495 (S.D.N.Y. 2007)). Takeda
 11 notes that TWi has not provided any evidence showing that the expired samples were not
 12 representative of its ANDA products. *Id.* (citing *Roche Palo Alto LLC v. Ranbaxy Labs., Inc.*,
 13 2009 WL 3261252 at *13 n.26 (D.N.J. Sept. 30, 2009)) [REDACTED]
 14 [REDACTED]
 15 [REDACTED] *Id.* (citing Purles Decl., Ex. 11 (Jun. 20,
 16 2012 Chen Dep. Tr.) at 176:6-8). As the Advantar tests were conducted within this [REDACTED]
 17 period, Takeda asserts, TWi cannot now assert that the test results are not relevant to its ANDA
 18 products. *Id.* Takeda also notes that TWi's expert, Dr. Gray, had the same batch tested as Dr.
 19 Charman. *Id.* (citing Purles Decl., Ex. 10 (Nov. 8, 2012 Gray Dep. Tr.) at 39:17-45:21
 20 (representation from TWi's counsel that the samples tested by Boston Analytical are from the
 21 same batch as the samples provided by TWi to Takeda); *id.*, Ex. 13 (Gray Rep. Ex. N) at 1
 22 (Boston Analytical Report, signed Oct. 18, 2012); Charman Rep. ¶ 82).

23 Finally, Takeda rejects TWi's contention that if Dr. Charman's approach is accepted the
 24 claim will be rendered indefinite, an argument that it contends was already rejected by the Court
 25 and has no merit. *Id.* at 16-18.

26 Accordingly, Takeda argues that TWi is not entitled to summary judgment of non-
 27 infringement of the '755 Patent because there is a genuine issue of material fact that must be
 28 resolved at trial.

1 c. TWi Reply

2 In its Reply brief, TWi reiterates its position that Dr. Charman's approach is not supported
3 by any acceptable scientific methodology, arguing that because the test was developed for
4 litigation, it is presumed to be inappropriate and Takeda bears the burden of showing that the
5 results are reliable -- a burden TWi contends has not been met. TWi Reply at 2 (citing *Cooper v.*
6 *Brown*, 510 F.3d 870, 944 n. 29 (9th Cir. 2007)). TWi rejects Takeda's explanation that in
7 developing the test, "Takeda and Advantar were guided by the fact that Dexilant is a preferred
8 embodiment of the '755 patent, and thus could be expected to meet the claim limitations." *Id.* at 4
9 (citing Takeda Opposition at 12). This approach is improper, according to TWi, because "[i]t is
10 legally impermissible to determine infringement by comparing an accused device to the
11 patentee's product." *Id.* (citing *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1347
12 (Fed. Cir. 2003)).

13 TWi also objects to Takeda's reliance on the declaration offered by Dr. Charman in support
14 of Takeda's opposition brief, in which he explains why he made certain choices in designing the
15 Advantar tests. *Id.* at 4-6. TWi contends Dr. Charman merely combined components from
16 various tests in the field, asserting that "Takeda's 'Frankenstein' dissolution test simply was not
17 the product of any acceptable scientific methodology." *Id.* at 5. TWi further asserts that Takeda
18 should be precluded from relying on the declaration because it is untimely. *Id.* at 5 (citing *Tokai*
19 *Corp. v. Easton Enters., Inc.*, 632 F.3d 1358 (Fed. Cir. 2011); *Yeti by Molly, Ltd. v. Deckers*
20 *Outdoor Corp.*, 259 F.3d 1101, 1106 (9th Cir. 2001); *Quevedo v. Trans-Pacific Shipping, Inc.*,
21 143 F.3d 1255, 1258 (9th Cir. 1998)). According to TWi, the declaration also should be
22 disregarded because it contradicts Dr. Charman's earlier testimony. *Id.* In particular, TWi points
23 to Dr. Charman's statement in his declaration that "[p]hotographs of the granules taken at the
24 conclusion of experiments, with and without SDS, demonstrate that SDS is interacting with the
25 enteric polymer in the coat of the low-pH granules...." *Id.* (citing Charman Decl. ¶ 22). TWi
26 asserts that Dr. Charman "expressed no such opinion in his report or at his deposition" and further
27 points to the following statements in the March 12, 2012 and May 9, 2012 Advantar reports that
28 TWi contends conflict with this opinion: 1) "The mechanism whereby SDS reduces lag time for

1 release is unknown.” *Id.* (citing Mizerk Decl., Ex. 17 at DEX1672899 (emphasis added); Mizerk
2 Decl., Ex. 1 at Ex. H at DEX1671969 (same)); 2) “The SDS effect does not appear to relate to
3 elevated solubility limits for DEX. Rather a direct effect on the granule enteric coating or possibly
4 granule contents seems *likely*.” *Id.* (citing Mizerk Decl., Ex. 17 at DEX1672901 (emphasis added
5 in TWi brief)); and 3) “Specifically, additional investigations should include the following: . . .
6 Further study of SDS effects on granule dissolution profiles.” *Id.* (citing Mizerk Decl., Ex. 17 at
7 DEX1672902). TWi contends that no further investigation was conducted on the effects of SDS
8 and that because Dr. Charman’s opinion in his declaration regarding the effects of the SDS is a
9 new opinion that contradicts his earlier report and deposition testimony, it should not be admitted.
10 *Id.* at 6 (citing *Chime v. PPG Indus., Inc.*, 402 F.3d 1371, 1381 (Fed. Cir. 2005); *Delaware*
11 *Valley Floral Group, Inc. v. Shaw Rose Nets, LLC*, 597 F.3d 1374, 1382 (Fed. Cir. 2010)).

12 Regarding the use of expired batches of TWi’s ANDA products for testing, [REDACTED]
13 [REDACTED]

14 *Id.* at 7. According to TWi, the cases cited in its motion establish that evidence based
15 on expired drug product is not relevant to infringement. *Id.* at 7 (citing *SmithKline Beecham*
16 *Corp. v. Apotex Corp.*, 2002 WL 1613724, at *2 (N.D. Ill. 2002); *Apotex, Inc. v. Cephalon, Inc.*,
17 2012 WL 1080148, *14 (E.D. Pa. Mar. 28, 2012)). Further, Takeda’s reliance on *In re*
18 *Omeprazole Patent Litig.*, 490 F. Supp. 2d 381 (S.D.N.Y. 2007) is misplaced, TWi argues,
19 because in that case, the party offering the testing provided additional testing that the expired
20 product continued to meet the approval specifications in the ANDA. *Id.* at 8. In other words, it is
21 Takeda’s burden, and not TWi’s, to show that the tests were representative of the ANDA
22 products. *Id.*

23 Finally, TWi reiterates its position that Takeda is improperly seeking a new claim
24 construction and that if the Court adopts Takeda’s proposed (new) construction, the asserted
25 claims of the ‘755 Patent will be rendered indefinite. *Id.* at 8-11.
26
27
28

1 III. ANALYSIS

2 A. Legal Standards

3 1. Legal Standard Governing Summary Judgment

4 Summary judgment on a claim or defense is appropriate “if the movant shows that there is
5 no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of
6 law.” Fed. R. Civ. P. 56(a). In order to prevail, a party moving for summary judgment must
7 show the absence of a genuine issue of material fact with respect to an essential element of the
8 non-moving party’s claim, or to a defense on which the non-moving party will bear the burden of
9 persuasion at trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Once the movant has
10 made this showing, the burden then shifts to the party opposing summary judgment to designate
11 “specific facts showing there is a genuine issue for trial.” *Id.* “[T]he inquiry involved in a ruling
12 on a motion for summary judgment . . . implicates the substantive evidentiary standard of proof
13 that would apply at the trial on the merits. *Anderson v. Liberty Lobby Inc.*, 477 U.S. 242, 252
14 (1986). On summary judgment, the court draws all reasonable factual inferences in favor of the
15 non-movant. *Id.* at 255.

16 2. Legal Standard Governing Infringement

17 A determination of infringement is a two-step process. *Wright Med. Tech., Inc. v.*
18 *Osteonics Corp.*, 122 F.3d 1440, 1443 (Fed. Cir. 1997). The first step is claim construction,
19 which is a question of law to be determined by the court. *Id.* The second step is an analysis of
20 infringement, in which it must be determined whether a particular device infringes a properly
21 construed claim. *Id.* A device literally infringes if each of the limitations of the asserted claim is
22 found in the accused device. *Id.* The patentee always bears the burden of proof on infringement.
23 *Under Sea Industries, Inc. v. Dacor Corp.*, 833 F.2d 1551, 1557 (Fed. Cir. 1987). Thus, a
24 patentee is entitled to summary judgment if it can show that it is “more likely than not” that the
25 accused product possesses all of the elements of the asserted claim. *Warner-Lambert Co. v. Teva*
26 *Pharms. USA, Inc.*, 418 F.3d 1326, 1341 (Fed. Cir. 2005) (citing *Anderson v. Liberty Lobby Inc.*,
27 477 U.S. at 252). Once the patentee has made a prima facie showing that it is more likely than
28 not that all the claim limitations are met, the accused infringer must come forward with more than

1 a scintilla of evidence to create a genuine issue of material fact as to non-infringement. *Id.*
 2 Conversely, an accused infringer is entitled to summary judgment of non-infringement where it
 3 shows “that the patentee failed to put forth evidence to support a finding that a limitation of the
 4 asserted claim was met by the structure in the accused devices.” *Johnston v. IVAC Corp.*,
 5 885 F.2d 1574, 1578 (Fed. Cir. 1989).

6 Takeda asserts its infringement claims under 35 U.S.C. § 271(e)(2); it also seeks a
 7 declaratory judgment of infringement and injunctive relief under 35 U.S.C. § 271(a) and the
 8 Declaratory Judgment Act. Section 271(e)(2) provides that:

9 [i]t shall be an act of infringement to submit . . . an [ANDA
 10 application to the FDA] . . . if the purpose of such submission is to
 11 obtain approval under such Act to engage in the commercial
 12 manufacture, use, or sale of a drug, veterinary biological product, or
 biological product claimed in a patent or the use of which is
 claimed in a patent before the expiration of such patent.

13 35 U.S.C. § 271(e)(2). Section 271(a) provides that “whoever without authority makes, uses,
 14 offers to sell, or sells any patented invention, within the United States or imports into the United
 15 States any patented invention during the term of the patent therefor, infringes the patent.” 35
 16 U.S.C. § 271(a).

17 3. Legal Standards Governing Invalidity

18 In a patent infringement action, the accused infringer bears the burden of proving
 19 invalidity of the asserted patent by clear and convincing evidence. *Central Admixture Pharmacy*
 20 *Services, Inc. v. Advanced Cardiac Solutions, P.C.*, 482 F.3d 1347, 1357-58 (Fed. Cir. 2007).

21 a. Anticipation

22 Under 35 U.S.C. § 102(a), a patent may be anticipated if the claimed invention was
 23 described in a printed publication “before the invention thereof by the applicant for patent.” 35
 24 U.S.C. § 102(a). The claim limitations may be disclosed “either expressly or inherently.” *EMI*
 25 *Group N. Am., Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1350 (Fed. Cir. 2001). “In
 26 general, a limitation or the entire invention is inherent and in the public domain if it is the ‘natural
 27 result flowing from’ the explicit disclosure of the prior art.” *Schering Corp. v. Geneva Pharms.*,
 28 339 F.3d 1373, 1379 (Fed. Cir. 2003) (citing *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955,

1 970 Fed. Cir. 2001); *In re Kratz*, 592 F.2d 1169, 1174 (CCPA 1979) (suggesting inherent
2 anticipation of a compound even though the compound's existence was not known)). In
3 *Continental Can Co. v. Monsanto Co.*, the Federal Circuit explained that "inherent" disclosure
4 "may not be established by probabilities or possibilities" but must be "necessarily present in the
5 thing described in the reference" as viewed by persons of ordinary skill in the art. 948 F.2d 1264,
6 1269 (Fed. Cir. 1991).

7 "[A]nticipation is a question of fact, including whether or not an element is inherent in the
8 prior art." *Eli Lilly and Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1375 (Fed. Cir.
9 2006). The accused infringer bears the burden of proving invalidity of the asserted patent by clear
10 and convincing evidence. *Microsoft Corp. v. i4i Ltd. Partnership*, 131 S. Ct. 2238 U.S. (2011).
11 In *Microsoft*, the Court explained that this heavy burden is based on § 282(a) of the Patent Act,
12 which provides that an issued patent "shall be presumed valid" and that "[t]he burden of
13 establishing invalidity ... rest[s] on the party asserting such invalidity." Nonetheless, in *Amgen*
14 *Inc. v. Hoechst Marion Roussel, Inc.* 314 F.3d 1313, 1354 (Fed. Cir. 2003) (*Amgen II*), the
15 Federal Circuit announced an exception to this rule, holding that a presumption of enablement
16 applies to both the claimed and unclaimed disclosures of prior art patents. *Amgen II*, 314 F.3d at
17 1355. Thus, the burden is on the *patentee* defending against an invalidity challenge based on a
18 prior art patent to "present persuasive evidence of non-enablement to overcome this
19 presumption." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1307 (2006) (*Amgen*
20 *III*).

21 The Federal Circuit in *Amgen II* reasoned as follows:

22 In patent prosecution the examiner is entitled to reject application
23 claims as anticipated by a prior art patent without conducting an
24 inquiry into whether or not that patent is enabled or whether or not
25 it is the claimed material (as opposed to the unclaimed disclosures)
26 in that patent that are at issue. . . . *In re Sasse*, 629 F.2d 675, 681,
27 207 USPQ 107, 111 (C.C.P.A.1980) ("[W]hen the PTO cited a
28 disclosure which expressly anticipated the present invention ... the
burden was shifted to the applicant. He had to rebut the
presumption of the operability of [the prior art patent] by a
preponderance of the evidence." (citation omitted)). The applicant,
however, can then overcome that rejection by proving that the

relevant disclosures of the prior art patent are not enabled. *Id.* We hold that an accused infringer should be similarly entitled to have the district court presume the enablement of unclaimed (and claimed) material in a prior art patent defendant asserts against a plaintiff. Thus, a court cannot ignore an asserted prior art patent in evaluating a defense of invalidity for anticipation, just because the accused infringer has not proven it enabled. Like the applicant in *ex parte* prosecution, however, the patentee may argue that the relevant claimed or unclaimed disclosures of a prior art patent are not enabled and therefore are not pertinent prior art. If a patentee presents evidence of nonenablement that a trial court finds persuasive, the trial court must then exclude that particular prior art patent in any anticipation inquiry, for then the presumption has been overcome.

Amgen II, 314 F.3d at 1355.

In a footnote, the Federal Circuit in *Amgen II* noted that “by logical extension, our reasoning here might also apply to prior art printed publications as well,” *id.* n. 22, and recently, in *In re Antor Media Corp.*, the Federal Circuit squarely held “that a prior art printed publication cited by an examiner is presumptively enabling barring any showing to the contrary by a patent applicant or patentee.” *Id.* at 1288. In *Antor*, the Federal Circuit rejected the patentee’s argument, based on § 282, that the presumption should not extend to non-patent prior art, explaining that in *Amgen*, the court did not rely only on § 282 as the source of the presumption but also on that fact that it is “procedurally convenient to place the burden on the applicant who is in a better position to show, by experiment or argument, why the disclosure in question is not enabling or operative.” *Id.*

Although the Federal Circuit in *Antor* addressed whether the presumption of enablement applied in the context of patent prosecution, the reasoning of that decision persuades the Court that the presumption also applies in the district court, just as the Federal Circuit found in *Amgen II* with respect to patent prior art cited to establish anticipation. Therefore, the Court finds that where a prior art printed publication is asserted in support of an anticipation defense, the prior art is presumed enabled unless the patentee can present “evidence of nonenablement that a trial court finds persuasive.” See *Amgen II*, 314 F.3d at 1355. Further, the Court concludes based on the *Amgen II* court’s reliance on *In re Sasse* that the amount of evidence required to rebut the

1 presumption is a preponderance of the evidence and that if the patentee meets that burden, the
 2 court must then exclude the prior art in its anticipation analysis. *See id*; *see also Amgen III*, 457
 3 F.3d at 1307 (noting that on remand, the district court found that the patentee met its “burden of
 4 proving by a preponderance of the evidence” that the prior art that was alleged to anticipate was
 5 not enabled and affirming the district court’s holding).

6 **b. Lack of Written Description**

7 The Patent Act requires that every patent must contain a written description and be
 8 enabled, as stated in 35 U.S.C. § 112 ¶ 1, which provides as follows:

9 The specification shall contain a written description of the
 10 invention, and of the manner and process of making and using it, in
 11 such full, clear, concise, and exact terms as to enable any person
 12 skilled in the art to which it pertains, or with which it is most nearly
 connected, to make and use the same, and shall set forth the best
 mode contemplated by the inventor of carrying out his invention.

13 To satisfy the written description requirement, “the description ‘must clearly allow persons of
 14 ordinary skill in the art to recognize that [the inventor] invented what is claimed.’” *Ariad*
 15 *Pharms., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (quoting *In re Gosteli*,
 16 872 F.2d 1008, 1012 (Fed. Cir. 1989)). “In other words, the test for sufficiency is whether the
 17 disclosure of the application relied upon reasonably conveys to those skilled in the art that the
 18 inventor had possession of the claimed subject matter as of the filing date.” *Id.* (quoting *Ralston*
 19 *Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575 (Fed. Cir. 1985)).

20 The Federal Circuit in *Ariad* acknowledged that the term “possession” “has never been
 21 very enlightening.” *Id.* It explained that “the hallmark of written description is disclosure” and
 22 that the “test requires an objective inquiry into the four corners of the specification from the
 23 perspective of a person of ordinary skill in the art.” *Id.* “For generic claims, [the Federal Circuit
 24 has] set forth a number of factors for evaluating the adequacy of the disclosure, including ‘the
 25 existing knowledge in the particular field, the extent and content of the prior art, the maturity of
 26 the science or technology, [and] the predictability of the aspect at issue.’” *Id.* Thus, the inquiry
 27 is a question of fact and is context-specific. *Id.* (citing *Ralston Purina*, 772 F.2d at 1575; *Capon*

1 v. *Eshhar*, 418 F.3d 1349, 1357–58 (Fed.Cir.2005)). However, certain “broad principles . . . hold
2 true across all cases.” *Id.* at 1352. The Federal Circuit described these principles as follows:

3 We have made clear that the written description requirement does
4 not demand either examples or an actual reduction to practice; a
5 constructive reduction to practice that in a definite way identifies
6 the claimed invention can satisfy the written description
7 requirement. *Falko–Gunter Falkner v. Inglis*, 448 F.3d 1357, 1366–
8 67 (Fed. Cir. 2006). Conversely, we have repeatedly stated that
9 actual “possession” or reduction to practice outside of the
10 specification is not enough. Rather, as stated above, it is the
11 specification itself that must demonstrate possession. And while the
12 description requirement does not demand any particular form of
13 disclosure, *Carnegie Mellon Univ. v. Hoffmann–La Roche Inc.*, 541
14 F.3d 1115, 1122 (Fed.Cir.2008), or that the specification recite the
15 claimed invention in haec verba, a description that merely renders
16 the invention obvious does not satisfy the requirement, *Lockwood v.*
17 *Am. Airlines*, 107 F.3d 1565, 1571–72 (Fed.Cir.1997).

18 *Id.* at 1352.

19 Finally, to meet the written description requirement, “[a]n applicant is not required to
20 describe in the specification every conceivable and possible future embodiment of his invention.”
21 *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1365 (Fed. Cir. 2003) (quoting *Rexnord*
22 *Corp. v. Laitram Corp.*, 274 F.3d 1336, 1344 (Fed. Cir. 2001)). Thus, “[a] specification may,
23 within the meaning of 35 U.S.C. § 112 para. 1, contain a written description of a broadly claimed
24 invention without describing all species that [the] claim encompasses.” *Id.* (quoting *Utter v.*
25 *Hiraga*, 845 F.2d 993, 998 (Fed. Cir.1988)). Further, “[a] patent need not teach, and preferably
26 omits, what is well known in the art.” *Epistar Corp. v. International Trade Commission*, 566
27 F.3d 1321, 1336 (Fed. Cir. 2009) (quoting *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524,
28 1534 (Fed. Cir. 2009)).

29 In *Ariad*, the Federal Circuit made clear that the written description requirement is distinct
30 from the enablement requirement, although the two “often rise and fall together.” 598 F.3d at
31 1352.

4. Legal Standards Governing Admissibility of Expert Testimony

The admissibility of expert testimony is governed by Rule 702 of the Federal Rules of Evidence, which provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

F.R.Evid. 702. In determining whether expert testimony meets the requirements of Rule 702, courts follow the approach set forth in *Daubert v. Merrell Dow Pharms., Inc.*, in which the Supreme Court described the relevant inquiry as follows:

Faced with a proffer of expert scientific testimony, then, the trial judge must determine . . . whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.

509 U.S. 579, 590 (1993). The Court declined to set forth a definitive list of factors, but offered some “general observations” about the types of factors that might be considered. *Id.* at 593.

These include: 1) whether the methodology can be or has been tested; 2) whether the theory and technique has been subjected to peer review; 3) if a “particular scientific technique” is involved, the known or potential rate of error; and 4) the degree of acceptance in the relevant scientific community. *Daubert*, 509 U.S. at 592-94.

If the basis for the expert’s opinion is clearly unreliable, the district court may disregard that opinion in deciding whether a party has created a genuine issue of material fact. See *id.* at 596 (if “the trial court concludes that the scintilla of [expert] evidence presented supporting a position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true, the court remains free to . . . grant summary judgment”).

1 The Ninth Circuit has held that a significant factor to be considered is “whether the
2 experts are proposing to testify about matters growing naturally and directly out of research they
3 have conducted independent of the litigation, or whether they have developed their opinions
4 expressly for purposes of testifying.” *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317
5 (9th Cir. 1995). Thus, “if the proffered expert testimony is not based on independent research, the
6 party proffering it must come forward with other objective, verifiable evidence that the testimony
7 is based on “scientifically valid principles.” *Id.* at 1317-1318; *see also Clausen v. M/V NEW*
8 *CARISSA*, 339 F.3d 1049 (9th Cir. 2003) (holding that even where scientific evidence is based on
9 research that was conducted for the purpose of testifying and was not subjected to normal
10 scientific scrutiny through peer review and publication, it may still be admissible if the experts
11 have explained “precisely how they went about reaching their conclusions and point[ed] to some
12 objective source -- a learned treatise, the policy statement of a professional association, a
13 published article in a reputable scientific journal or the like -- to show that they have followed the
14 scientific evidence method, as it is practiced by (at least) a recognized minority of scientists in
15 their field.”).

16 The determination of reliability is left to the discretion of the district court, consistent with
17 its gatekeeping function under Rule 702. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 149
18 (1999).

19 **B. Infringement of the ‘282 Patent**

20 **1. Existence of Subject Matter Jurisdictions**

21 TWi contends that there is no subject matter jurisdiction over Takeda’s ‘282 Patent
22 infringement claim under 35 U.S.C. §271(e)(2) because Takeda did not list that patent in the
23 Orange Book. The Court disagrees.

24 The Hatch-Waxman Act gives manufacturers of generic drugs a safe harbor in which to
25 develop their products without threat of patent litigation. See 35 U.S.C. § 271(e)(1). In return,
26 Congress gave patentees the right to challenge a generic drug when the generic manufacturer files
27 an ANDA, deeming the filing of the ANDA “a defined act of infringement sufficient to create
28 case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning

1 infringement and validity.” *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir.1997).

2 This compromise is embodied in subsections (1) and (2) of 35 U.S.C. § 271(e), which provides, in
3 relevant part as follows:

4 (e)(1) It shall not be an act of infringement to make, use, offer to
5 sell, or sell within the United States or import into the United States
6 a patented invention (other than a new animal drug or veterinary
7 biological product (as those terms are used in the Federal Food,
8 Drug, and Cosmetic Act and the Act of March 4, 1913) which is
9 primarily manufactured using recombinant DNA, recombinant
10 RNA, hybridoma technology, or other processes involving site
specific genetic manipulation techniques) solely for uses reasonably
related to the development and submission of information under a
Federal law which regulates the manufacture, use, or sale of drugs
or veterinary biological products.

11 (2) It shall be an act of infringement to submit--

12 (A) an application under section 505(j) of the Federal Food, Drug,
13 and Cosmetic Act or described in section 505(b)(2) of such Act for
14 a drug claimed in a patent or the use of which is claimed in a patent,
...

15 if the purpose of such submission is to obtain approval under such
16 Act to engage in the commercial manufacture, use, or sale of a drug,
17 veterinary biological product, or biological product claimed in a
18 patent or the use of which is claimed in a patent before the
expiration of such patent.

19 35 U.S.C. § 271(e) (1) & (2).

20 Further, “the Hatch-Waxman Act . . . establishes a procedure called a ‘Paragraph IV
21 certification,’ 21 U.S.C. § 355(j)(2)(A)(vii)(IV), by which an entity that seeks to market a generic
22 counterpart of a patented drug product or method of use, before the patent has expired, may
23 challenge the patent before actually marketing the drug.” *Cephalon, Inc. v. Watson Pharms., Inc.*,
24 707 F.3d 1330 (Fed. Cir. 2013). As part of this procedure, most patentees and New Drug
25 Applicant (“NDA”) holders are required to list patents related to their approved drugs in the
26 FDA’s “Approved Drug Products with Therapeutic Equivalence Evaluations” publication (the
27 “Orange Book”). 21 U.S.C. § 355(b)(1). A company that manufactures generic drugs, in turn, is
28 required to consult the Orange Book before filing an ANDA and certify that either (I) no patent

1 information is listed in the Orange Book for the proposed generic drug; (II) that the listed patents
2 have expired; (III) that the listed patents will expire before the generic company markets its
3 product; or (IV) that the patents listed are invalid or will not be infringed by the generic drug (a
4 "paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV).

5 Here, Takeda has alleged jurisdiction under 28 U.S.C. § 1338, which provides that "[t]he
6 district courts shall have original jurisdiction of any civil action arising under any Act of Congress
7 relating to patents." Thus, the existence of subject matter jurisdiction over Takeda's § 271(e)(2)
8 claim based on the '282 Patent depends on whether that claim "arises under" the Hatch-Waxman
9 Act even though TWI's ANDA did not include a Paragraph IV certification. Some courts have
10 found that a Paragraph IV certification is a jurisdictional requirement for bringing a claim under
11 the Hatch-Waxman Act. *See, e.g., Eisai Co. v. Mutual Pharmaceutical Co., Inc.*, 2007 WL
12 4556958 (D.N.J. Dec. 20, 2007). In *Eisai*, the court recognized that "[t]he plain text of §
13 271(e)(2) does not require that the alleged infringer file an ANDA with a Paragraph IV
14 certification, or that the drug claims be listed in the Orange Book." *See* 2007 WL 4556958, at *9.
15 Nonetheless, based on extended discussion of the ANDA process in decisions by the Federal
16 Circuit, the *Eisai* court concluded that a Paragraph IV requirement should be "read into" §
17 271(e)(2). *Id.* at * 12.

18 The undersigned does not find the reasoning of *Eisai* persuasive given the clear language
19 of the statute and the fact that none of the Federal Circuit cases addressed in *Eisai* directly
20 addressed the question of whether a Paragraph IV certification was required in order for a
21 patentee to bring an infringement claim under the Hatch-Waxman Act. *See id.* at *11 ("The
22 Federal Circuit has never squarely faced the question before this Court"). The Federal Circuit
23 subsequently resolved any doubt on this issue in *AstraZeneca Pharms. LP v. Apotex Corp.*, 669
24 F.3d 1370 (Fed. Cir. 2012). In *AstraZeneca*, the Federal Circuit held that under the Hatch-
25 Waxman Act, "the requirements for jurisdiction in the district courts are met once a patent owner
26 alleges that another's filing of an ANDA infringes its patent under § 271(e)(2), and this threshold
27 jurisdictional determination does not depend on the ultimate merits of the claims." 669 F.3d at
28 1376-77.

Further, in *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670 (2012), the Supreme Court also made clear that a Paragraph IV certification is not a jurisdictional requirement for bringing an action under the Hatch-Waxman Act. In that case, the generic drug manufacturer, *Caraco*, initially included a Paragraph IV certification in its ANDA but later inserted a statement under § 355(j)(2)(A)(viii) (“section viii statement”). 132 S. Ct. at 1679. A section viii statement asserts that the generic manufacturer will market the drug for one or more methods of use not covered by the brand’s patents and is an alternative to a Paragraph IV certification for obtaining FDA approval. *Id.* at 1677-1678. Before the FDA had approved the generic on the basis of the section viii statement, however, the patentee, Novo, amended its use codes to cover the uses for which the generic manufacturer sought approval. *Id.* at 1679. In the ensuing Hatch-Waxman infringement action initiated by Novo, the generic manufacturer asserted a counterclaim seeking to compel Novo to amend its use codes such that *Caraco* would be able to obtain FDA approval under section viii rather than under Paragraph IV. The question before the Supreme Court was whether *Caraco* could assert such a counterclaim. In that context, Novo argued that there was no subject matter jurisdiction over the action. 132 S. Ct. 1670, 1680 n.5 (2012). The Court rejected that argument, reasoning as follows:

On Novo’s theory, [a section viii] statement (unlike a paragraph IV certification) does not count as an act of infringement under the patent statute, see 35 U.S.C. § 271(e)(2)(A), and so cannot provide a jurisdictional basis for the suit. But that argument is wrong even assuming (as Novo contends) that *Caraco*’s section viii filing terminated its paragraph IV certification and that a section viii filing is not an act of infringement. The want of an infringing act is a merits problem, not a jurisdictional one. Nothing in the section of the statute defining certain filings as acts of infringement suggests anything to the contrary. And “we are not inclined to interpret statutes as creating a jurisdictional bar when they are not framed as such.” *Stern v. Marshall*, 564 U.S. —, —, 131 S. Ct. 2594, 2607, 180 L.Ed.2d 475 (2011). In the absence of such a bar, the federal courts have jurisdiction over this suit for a single, simple reason: It “ar[ose] under a[n] Act of Congress relating to patents.” 28 U.S.C. § 1338(a):

Id.

1 In light of the *Caraco* decision and the Federal Circuit's recent decision in *Astrazeneca*,
 2 this Court joins a number of other district courts in concluding that there is no requirement under
 3 the Hatch-Waxman Act that a patent must be listed in the Orange Book in order for a drug
 4 manufacturer to bring an infringement action based on that patent against an ANDA applicant.
 5 See *Merck Sharp & Dohme Corp. v. Sandoz Inc.*, 2013 WL 591976 (D.N.J. Feb. 14, 2013)
 6 (declining to follow *Eisai* on the basis that "more recent precedent of the Federal Circuit controls"
 7 and holding that under *AstraZeneca* it is clear that the requirements for jurisdiction in the district
 8 courts are met once a patent owner alleges that the filing of an ANDA infringes its patent under §
 9 271(e)(2), regardless of whether the ANDA includes a Paragraph IV certification); *Cephalon*,
 10 *Inc. v. Sandoz, Inc.*, 2012 WL 682045, at *5 (D. Del. Mar. 1, 2012) (rejecting the reasoning and
 11 "sweeping conclusion" of *Eisai* that the court lacked jurisdiction under the Hatch-Waxman Act
 12 where there was no paragraph IV certification); *Purdue Pharma Prods. L.P. v. Par Pharm., Inc.*,
 13 642 F. Supp. 2d 329, 363 n.49 (D. Del. 2009) (holding that "[t]here is no requirement that
 14 infringement actions against ANDA filers must be based on patents listed in the Orange Book");
 15 *Teva Pharms. USA, Inc. v. Abbott Labs.*, 301 F. Supp. 2d 819, 829 (N.D. Ill. 2004) ("The
 16 language of § 271(e)(2)(A) does not require that the ANDA contain a [paragraph IV] certification
 17 to constitute an act of infringement. It only requires that the [ANDA] application be filed under §
 18 355(j)"); *Bayer Healthcare, LLC v. Norbrook Labs., Ltd.*, 2009 WL 6337911, at *9 (E.D. Wis.
 19 Sept. 24, 2009) (holding in a case involving an Abbreviated New Animal Drug Application that
 20 "a paragraph IV certification is not required to trigger an infringement action under § 271(e)(2)").

21 Therefore, the Court concludes that it has subject matter jurisdiction over Takeda's
 22 infringement claim under § 271(e)(2) even though the '282 Patent was not listed in the Orange
 23 Book.

24 2. Whether Takeda has Established Infringement

25 Takeda seeks summary judgment of infringement of the '282 Patent based on what it
 26 contends is substantial evidence that TWI's ANDA products contain amorphous dextansoprazole.
 27 Takeda relies primarily on TWI's statements, both to the FDA and in this litigation, rather than on
 28 its own testing of the ANDA products. For the reasons discussed below, the Court concludes that

1 this evidence is sufficient to find, as a matter of law, that TWi's ANDA products contain
2 amorphous dextansoprazole and therefore, that Takeda is entitled to summary judgment of
3 infringement of the '282 Patent under the Hatch-Waxman Act (Count IV). The Court declines to
4 enter summary judgment in Takeda's favor on Count VII, however, because Takeda has not
5 established that it meets the constitutional requirements for bringing claims under the Declaratory
6 Judgment Act.

7 To establish a case or controversy under Article III of the U.S. Constitution, a claim must
8 be "'definite and concrete, touching the legal relations of parties having adverse legal interests';
9 and that it be 'real and substantial' and 'admi[t] of specific relief through a decree of a conclusive
10 character, as distinguished from an opinion advising what the law would be upon a hypothetical
11 state of facts.'" *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007)(quotations
12 omitted). Some courts have permitted claims seeking declaratory judgment of infringement under
13 § 271(a) based on the filing of an ANDA. *See, e.g., Cephalon v. Sandoz, Inc.*, 2012 WL 682045 ,
14 at *5 (D. Del. Mar. 1, 2012); *Bayer Healthcare, LLC v. Norbrook Labs., Ltd.*, 2009 WL
15 6337911, at *13-14 (E.D. Wis. Sept. 24, 2009). Other courts, however, have held that such
16 claims are not sufficiently real and immediate to satisfy the requirements of *MedImmune*. *See,*
17 *e.g., Eisai*, 2007 WL 4556958 (D.N.J. Dec. 20, 2007); *see also Abbott Labs. v. Zenith Labs., Inc.*,
18 934 F. Supp. 925, 983 (N.D. Ill. 1995) (questioning whether such a claim is consistent with
19 Congress' intent in providing a safe haven for generic manufacturers under the Hatch-Waxman
20 Act). Although TWi alluded to this issue in its Reply brief, Takeda did not have an opportunity to
21 respond on this question. Therefore, the Court does not reach the question of whether Takeda can
22 establish the existence of a "definite and concrete" controversy on its infringement claims under §
23 271(a) and the Declaratory Judgment Act. The Court now turns to the substantive question of
24 whether Takeda is entitled to summary judgment that TWi's ANDA products contain amorphous
25 dextansoprazole.

26 "A patentee may prove infringement by 'any method of analysis that is probative of the
27 fact of infringement' . . . , and circumstantial evidence may be sufficient." *Martek Biosciences*
28 *Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1372 (Fed. Cir. 2009) (citing *Forest Labs. v. Abbott*

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1 *Labs.*, 239 F.3d 1305, 1312 (Fed. Cir. 2001), *Liquid Dynamics Corp. v. Vaughan Co., Inc.*, 449
2 F.3d 1209, 1219 (Fed. Cir. 2006)). Further, “[b]ecause drug manufacturers are bound by strict
3 statutory provisions to sell only those products that comport with the ANDA’s description of the
4 drug, an ANDA specification defining a proposed generic drug in a manner that directly addresses
5 the issue of infringement will control the infringement inquiry.” *Abbott Labs. v. TorPharm, Inc.*,
6 300 F.3d 1367, 1373 (Fed. Cir. 2002); see also *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*,
7 491 F.3d 1342, 1351 (Fed. Cir. 2007)(“[t]here is no prohibition against using the admissions of a
8 party, whether in the form of marketing materials or otherwise, as evidence in an infringement
9 action”). Whether a statement made in a party’s legal brief is considered a binding judicial
10 admission is within the discretion of the court. *Gospel Missions of America v. City of Los Angeles*,
11 328 F.3d 548, 557 (9th Cir. 2003).

12 In light of the rule stated in *Abbott*, the Court looks first to TWi’s statement to the FDA in
13 its ANDA describing its choice of layering process [REDACTED]

14 [REDACTED]
15 [REDACTED] see Myerson Decl., Ex. 8 (Chen Dep. Ex. 51), at ANC-DEXL0000779;
16 JSUF (Takeda Motion) ¶ 11. Given that it is undisputed that the dexlansoprazole used in the
17 manufacture of the ANDA products is amorphous dexlansoprazole, this statement is sufficient to
18 establish that the finished product also contains amorphous dexlansoprazole.

19 Further, even if the statement to the FDA in the ANDA did not, by itself, require such a
20 finding, the Court further finds that Takeda is entitled to summary judgment on this question
21 because TWi’s statements in this litigation also establish that its ANDA products more likely than
22 not contains amorphous dexlansoprazole. These statements include: 1) deposition testimony by
23 Dr. Shou-Chiung Chen, TWi’s 30(b)(6) witness, [REDACTED]
24 [REDACTED] see Myerson Decl., Ex. 7 (Jun. 20, 2012 Chen Dep. Tr. 118:1-
25 10, 123:24-124:6-8); 2) TWi’s interrogatory responses stating that its “ANDA drug products do
26 not contain a crystal or crystalline compound of dexlansoprazole . . .,” see Myerson Decl., Ex. 9
27 (TWi’s Responses and Objections to Plaintiff’s First Set of Joint Interrogatories, July 28, 2011) at
28 17; 3) TWi’s paragraph IV letter to Takeda, which stated that “the ANDA drug products do not

1 include a crystal or crystalline compound of dextansoprazole.” See Myerson Decl., Ex. 10
2 (ANCDEXL0000238-277), at ANC-DEXL0000258.

3 In reaching this conclusion, the Court rejects TWi’s suggestion it should find that there is a
4 material dispute of fact because the dextansoprazole in the ANDA products *might* be molecular
5 dextansoprazole rather than an amorphous solid. The only evidence in the record indicates that
6 the dextansoprazole in the ANDA products is a solid; indeed, TWi characterized it as such in its
7 ANDA. See Myerson Decl., Ex. 3, at ANC-DEXL0000438 (indicating that excipients used in
8 ANDA products fell below “limits for solid, oral dosage forms”); Myerson Decl., Ex. 8, at ANC-
9 DEXL0000769 (same); Takahashi Reply Decl., Ex. 3 (ANC-DEL0000796) (statement in ANDA
10 that a particular test was not performed on the ANDA products because it is “[n]ot applicable for
11 solid oral dosage forms”). Further, there is substantial evidence in the record that a solid form of
12 dextansoprazole must be either amorphous or crystalline. See Myerson Claim Construction Decl.
13 ¶ 81 (“Solids can be crystalline or amorphous.”), ¶ 23 (“Solids that are not crystalline and have no
14 long range order . . . are said to be amorphous.”); Myerson Rep. ¶ 22 (same); Myerson Claim
15 Construction Decl. Ex. 11 at DEX0014516 (“The terms amorphous and non-crystalline are
16 synonymous . . . and can be used interchangeably.”); *id.*, Ex. 12, at DEX0014612 (“[N]ot all
17 solids are crystals. Materials that have short-range rather than long range ordering . . . are non-
18 crystalline solids. A noncrystalline solid is often referred to as an amorphous solid.”); *id.*, Ex. 13
19 at DEX0014769 (“A liquid may solidify in two ways: . . . to a crystalline solid or . . . to an
20 amorphous solid.”); *id.*, Ex. 27, at DEX0014491 (defining “[a]morphous [s]olid” as “[a]
21 noncrystalline solid”); Rogers Claim Construction Decl., Ex. 3, at DEX0003649 (“Some authors
22 [] sub-divide solids into crystalline and amorphous.”); *id.*, Ex. 4 at IPXL-0009902 (defining
23 “amorphous” as “[n]oncrystalline . . .”); *id.*, Ex. 5 at IPXL-0010285 (same); Takahashi Reply
24 Decl., Ex. 2 (Dec. 9, 2011 Rogers Dep.) at 19:5-13; Rogers Claim Construction Decl. ¶ 30
25 (“[T]he term ‘amorphous’ is an adjective that is synonymous with ‘noncrystalline.’”); *id.*, ¶¶ 28-
26 29).

27 Because the Court finds that TWi has not identified specific facts establishing the existence
28 of a genuine issue of material fact as to whether its ANDA products contain the claimed

1 amorphous dextansoprazole, the Court concludes that Takeda is entitled to summary judgment of
2 infringement of the '282 Patent by TWi's ANDA products under the Hatch-Waxman Act (Count
3 IV). Further, if Takeda can establish at trial that it has standing under the Declaratory Judgment
4 Act, it will be entitled to judgment in its favor on Count VII as well.

5 **C. Validity of the '282 Patent**

6 **1. Anticipation**

7 TWi argues that the '282 Patent is anticipated by the Larsson and Barberich references.
8 This dispute turns primarily on two questions: 1) whether Larsson inherently discloses an
9 amorphous salt of dextansoprazole, as is required under claim 1 of the '282 Patent; and 2)
10 whether the disclosure of such a salt is enabled. The Court finds that this feature is not inherently
11 disclosed in Larsson, which therefore does not anticipate the asserted claims of the '282 Patent.
12 The Court further finds that although a solid salt of dextansoprazole is disclosed in Barberich,
13 ~~there is a fact question as to whether the disclosure is enabled and therefore, summary judgment~~
14 on the question of whether Barberich anticipates the asserted claims of the '282 Patent is
15 inappropriate.

16 In support of its contention that Larsson inherently discloses making a salt of
17 dextansoprazole consistent with the Court's claim construction, which requires that the salt must
18 be a solid, TWi cites Dr. Atwood's testimony that "typically" one would expect a salt of
19 dextansoprazole made through conventional processes to be a solid. This evidence is insufficient
20 to establish inherent disclosure. As stated above, inherent disclosure may not be established by
21 "probabilities or possibilities." *Bettcher Industries, Inc. v. Bunzl USA, Inc.*, 661 F.3d 629, 639
22 (Fed. Cir. 2011) (quoting *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981)). "The mere fact that a
23 certain thing may result from a given set of circumstances is not sufficient." *Id.* For example, in
24 *Glaxo Inc. v. Novapharm Ltd.*, the defendant argued that the asserted patent was anticipated based
25 on inherent disclosure in the prior art, citing evidence that its expert had reproduced the prior art
26 method thirteen times, each time obtaining the claimed crystals. 52 F.3d 1043, 1047 (Fed. Cir.
27 1995). However, the patentee had presented evidence that two of its own experts had used the
28 same method to produce different crystals. *Id.* Because the method described in the prior art did

1 not “always yield” the claimed invention but rather, “*could* yield” something different, the
2 Federal Circuit affirmed the district court’s holding that there was no inherent disclosure and
3 therefore, that the asserted patent was not anticipated. *Id.*

4 Dr. Atwood did not testify that conventional processes for making a salt of
5 dextansoprazole always result in a solid salt of dextansoprazole, as is claimed in the ‘282 Patent.
6 To the contrary, he testified that such processes will not always result in a salt that is a solid.
7 Thus, his testimony does not establish inherent disclosure. Nor does Dr. Atwood’s testimony that
8 one would “typically” expect a solid give rise to a “presumption that the Larsson and Barberich
9 references disclose the claimed solid dextansoprazole salts.” See TWi Reply at 14. TWi’s
10 reliance on *In re Antor Media Corp.*, 689 F.3d 1282, 1288 Fed. Cir. 2012) in support of this
11 assertion is misplaced. That case addressed the presumption of *enablement* that the Federal
12 Circuit found applies to a printed prior art publication during patent prosecution. It did not
13 address the question of inherent disclosure of an allegedly anticipating reference. In the absence
14 of disclosure of the claimed *solid* salt of dextansoprazole, the Court does not reach the question of
15 enablement as to Larsson.

16 On the other hand, it is undisputed that a solid amorphous compound of dextansoprazole is
17 disclosed in Barberich. Further, Takeda does not dispute that a person skilled in the art at the
18 priority date would have known how to obtain “a salt thereof” and that a salt obtained from a
19 solid amorphous compound would also be a solid. Therefore, the Court finds that the “salt
20 thereof” of claim 1 is disclosed in Barberich. The question of whether Barberich anticipates the
21 ‘282 Patent, then, turns on enablement, that is, whether a person of ordinary skill in the art could
22 create a salt of an amorphous compound of dextansoprazole (which must be solid under the
23 Court’s claim construction) based on the disclosure in Barberich. As it is undisputed that a
24 person of ordinary skill knew how to obtain a salt and that a salt made from a solid amorphous
25 compound of dextansoprazole would also be solid, the only remaining question is whether a
26 person of ordinary skill in the art would have been enabled as to creating the claimed amorphous
27 compound of dextansoprazole, which must be a solid under the Court’s claim construction.
28 Barberich does not offer any guidance on how to create such a compound, instead incorporating

1 Larsson. The only guidance in Larsson, however, is set forth in Example 22. For the reasons set
2 forth in the Court's Order in related case C-11-0840, the Court finds that there is a fact question
3 as to whether the disclosure in Larsson would be sufficient to create the claimed amorphous
4 compound without undue experimentation.¹⁴ Therefore, there is also a fact question as to whether
5 the claimed amorphous solid salt of dextansoprazole disclosed in Barberich is enabled.
6 Accordingly, summary judgment on this question is not appropriate.

7 2. Lack of Written Description

8 TWi contends that Takeda's anticipation argument, if credited, leads to the conclusion that
9 the '282 Patent lacks sufficient written description because it does not describe how the solid salt
10 of dextansoprazole is created. TWi's position fails because it is undisputed that a person of skill
11 in the art would know how to derive a salt of amorphous dextansoprazole. Because the '282
12 Patent also describes the synthesis of an amorphous compound of dextansoprazole that is solid,
13 ~~this disclosure shows that the inventors were in possession of the claimed salt of dextansoprazole,~~
14 which was a solid rather than an oil. Therefore, TWi is not entitled to summary judgment of
15 invalidity on this basis.

16 D. Infringement of the '755 Patent

17 1. Whether Dr. Charman's Opinions Should be Excluded Under *Daubert*

18 TWi argues that Dr. Charman's opinions are not supported by any scientifically acceptable
19 methodology and are based on what it colorfully describes as a "Frankenstein" dissolution test. In
20 support of its position, TWi relies primarily on the fact that the test methodology was developed
21 for litigation. It dismisses the explanation offered by Dr. Charman in his opposition declaration,
22 in which he sets forth his reasons for adopting the protocol that was used by Advantar, as an
23 untimely attempt to survive TWi's *Daubert* motion by articulating new opinions that conflict with
24 Dr. Charman's earlier report. The Court finds TWi's arguments unpersuasive.

25 As a preliminary matter, the Court addresses whether the declaration of Dr. Charman in
26 supported of Takeda's opposition should be excluded. TWi appears to seek exclusion of this
27

28 ¹⁴ In its Motion, TWi expressly joined in the invalidity arguments set forth in Handa's summary
judgment motion. See TWi SJ Motion at 15 n. 9.

1 declaration as a discovery sanction, pursuant to Rule 37 of the Federal Rules of Civil Procedure.¹⁵
 2 The Federal Circuit has noted that “Rule 37(c)(1) ‘gives teeth’ to the written report requirement of
 3 Rule 26(a)(2)(B) by forbidding a party’s use of improperly disclosed information at a trial, at a
 4 hearing, or on a motion, unless the party’s failure to disclose is substantially justified or
 5 harmless.” *Tokai Corp. v. Easton Enterprises, Inc.*, 632 F.3d 1358, 1365 (Fed. Cir. 2011) (citing
 6 *Yeti By Molly Ltd. v. Deckers Outdoor Corp.*, 259 F.3d 1101, 1106 (9th Cir. 2001)). TWi
 7 contends that Dr. Charman’s declaration contains new opinions that conflict with his expert report
 8 or at least were not disclosed in them. TWi points to only one concrete example of a new opinion
 9 however, namely, Dr. Charman’s statement that “[p]hotographs of the granules taken at the
 10 conclusion of experiments, with and without SDS, demonstrate that SDS is interacting with the
 11 enteric polymer in the coat of the low-pH granules....” *Id.* (citing Charman Decl. ¶ 22). This
 12 opinion is new and contradictory, according to TWi, because it was not expressed in Dr.
 13 Charman’s report, and the Advantar documents upon which Dr. Charman relied stated only that it
 14 was “likely” that the effect of the SDS in the earlier tests resulted from its “effect on the granule
 15 enteric coating or possibly granule contents.” *See Mizerk Decl.*, Ex. 17 at DEX1672901. The
 16 Court finds that this variation in the degree of certainty as to reason for the SDS effect in the
 17 earlier Advantar tests is insignificant and does not represent the sort of new and undisclosed
 18 opinion that would warrant exclusion under Rule 37. The Court further notes that TWi’s counsel
 19 had the opportunity to depose Dr. Charman after Dr. Charman had reviewed the earlier test
 20 protocols. Therefore, the Court does not find that the Charman opposition declaration should be
 21 excluded.

22 The Court also rejects TWi’s contention that Dr. Charman’s tests are not supported by any
 23 acceptable scientific methodology. TWi’s position is largely based on unsupported accusations
 24 and innuendo. It makes much of the fact that at his November 11, 2011 deposition, Dr. Charman
 25 testified, when asked what experiments he would conduct to determine whether a product met his
 26 proposed claim construction, that he had not “considered the experiments that one may undertake

27 ¹⁵ The Court notes that to the extent TWi seeks exclusion of the Charman opposition declaration
 28 as a discovery sanction, it has failed to adhere to the Local Rules of this district, which require
 that a request for sanctions must be set forth in a separately filed motion. *See Civ. L. R. 7-2.*

1 in order to meet the proposed claim construction” because this was outside the scope of what he
 2 had been asked to address in the context of claim construction. *See* Purles Decl., Ex. 12 at 112.
 3 TWi suggests that when Dr. Charman did eventually develop a test protocol, it was created only
 4 to ensure that the results would support Takeda’s position and not for any scientifically valid
 5 reasons; it is for this reason, according to TWi, that Dr. Charman chose to conduct the Advantar
 6 tests upon which he relied without SDS.

7 Dr. Charman’s report, however, as well as the Advantar report cited therein, provides
 8 scientific reasons for choosing to conduct the Advantar tests without SDS. *See* Charman Decl.,
 9 Ex. B (Charman Report Regarding Infringement by TWi) ¶ 71 & Ex. 3 (Advantar Aug. 23, 2012
 10 Report) at DEX1668807. In particular, in his report, Dr. Charman states as follows:

11 Due to lansoprazole’s low solubility in water, compendial (USP)
 12 monograph methods for release from lansoprazole capsules include
 13 surfactant (sodium dodecyl sulfate or “SDS”) in the dissolution
 14 medium to enhance dissolution. The quantities of granules used in
 15 Advantar’s experiments, however, were such that dextralansoprazole’s
 solubility was not exceeded. Therefore, SDS, which is not found in
 the GI environment into which the drug is ingested, was neither
 required nor included in the dissolution medium.

16 Charman Report (TWi) ¶ 71 (citing Advantar Aug. 23, 2012 Report at 2). TWi does not point to
 17 any expert testimony that addresses these reasons or explains why they are not scientifically valid.
 18 Under these circumstances, the Court concludes that Dr. Charman’s opinions based on the
 19 Advantar tests are admissible, even though those tests were conducted within the context of
 20 litigation and have not been subjected to peer review, because Dr. Charman has provided
 21 scientific reasons in support of his protocol and TWi has not cited expert testimony establishing
 22 (or even opining) that those reasons are not based on scientifically valid principles. *See Daubert*
 23 *v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995).

24 The Court rejects TWi’s *Daubert* challenges.

25 2. Whether Test Results Establish Non-Infringement

26 TWi contends that even if the Court finds that Dr. Charman’s opinions based on the
 27 Advantar tests are admissible, the results of those tests establish, as a matter of law, that TWi’s
 28 ANDA products do not infringe the asserted claims of the ‘755 Patent. Because the Court finds

1 that Takeda's position on this issue amounts to a request for a revised construction of the release
2 term, the Court first addresses whether such a revision is appropriate.¹⁶ Having carefully
3 considered the supplemental claim construction briefs and supporting materials filed by the
4 parties in this action and the related actions, the Court declines to revise its previous construction.
5 Further, the Court finds that under that construction, the undisputed facts establish, as a matter of
6 law, that TWi's ANDA products do not infringe the asserted claims of the '755 Patent.

7 As noted above, at the claim construction stage of the case, the Court construed the phrase
8 "released in the pH range of no less than 5.0 to no more than 6.0" to mean "begins to be released
9 from the tablet, granule or fine granule at pH values within the range from 5.0 to 6.0." The
10 Court's construction makes clear that the range set forth in the release term is a threshold at which
11 release begins. The Court acknowledged in its claim construction order that the parties disagree
12 about what testing should be conducted to determine infringement but found that this
13 disagreement goes to infringement rather than indefiniteness, rejecting the defendants' argument
14 that a person skilled in the art would not know how to determine when release "begins." Now,
15 however, Takeda argues that there is a fact question on infringement -- even though the
16 undisputed evidence (Takeda's own testing) shows measurable dissolution of the API of TWi's
17 ANDA product at pH levels below 5.0 -- because the release is not significant and rapid;
18 according to Takeda's expert, such release does not occur unless at least 10% of the drug is
19 released in a 2-hour period. Takeda is essentially asking the Court to adopt a broader construction
20 of the release term than it adopted in its claim construction order. In light of the intrinsic
21 evidence, the Court concludes that Takeda's position is incorrect.

22 First, the Court looks to the claim language. "Absent an express intent to impart a novel
23 meaning, claim terms take on their ordinary meaning." *Elekta Instrument S.A. v. O.U.R. Scientific*
24 *International, Inc.*, 214 F.3d 1302, 1307 (Fed. Cir. 2000) (citation omitted). The plain language
25 of the release term of claim 1 sets forth a specific range of pH values in which release of the API
26 must begin. This range captures the idea set forth in the specification that composition (ii)

27
28 ¹⁶ The general legal standards governing claim construction are set forth in the Court's claim construction order. See Docket No. 81. Therefore, the Court does not repeat them here.

1 dissolves at a pH of "about 5.5." See '755 Patent, col. 2, ll. 48-53 (stating in the "Disclosure of
2 Invention" section that the invention provides a "capsule . . . which comprises a tablet, granule or
3 fine granule having an enteric coat that releases an active ingredient at the pH of about 5.5"). In
4 other words, the claim language *already* allows for some dissolution to occur below the 5.5 target
5 pH level for composition (ii) while remaining within the scope of the claim. Were the Court to
6 insert further qualifying language in its construction that allowed release *below* the lower end of
7 the range claimed by the inventors, it would not only be ignoring the ordinary meaning of the
8 claim term but would also be rendering the lower end of the range in the claim superfluous to the
9 extent that release would be permitted both below 5.0 *and* above 5.0. See *Elekta*, 214 F.3d at
10 1307 (reversing district court's construction of the term "only within a zone extending between
11 latitudes 30° - 45°" as meaning "beginning at the edge of the helmet (0°) and extending to a point
12 between 30° - 45°" on the basis that it was inconsistent with ordinary meaning of claim language
13 and rendered lower end of the range superfluous); *U.S. Philips Corp. v. Isasaki Elec. Co.*, 505
14 F.3d 1371, 1376 (Fed. Cir. 2007) (affirming district court's construction of term "between 10⁻⁶
15 and 10⁻⁴ <<mu>>mol/mm³" as meaning "between 1 x 10⁻⁶ and 1 x 10⁻⁴⁴ <<mu>>mol/mm³" and
16 noting that district court was correct that "the overall phrase - 'a quantity between -- and --' - is a
17 construction that 'implies a specific range . . . it does not imply a range between two values which
18 are themselves ranges"). Thus, the unambiguous language of the claim supports a construction
19 that does not permit release of the API outside of the claimed range.

20 Further, nothing in the prosecution history or the specification of the '755 Patent persuades
21 the Court that it is appropriate to read into the release term a requirement that release must be
22 significant and rapid (or to state it somewhat differently, that the claim covers embodiments in
23 which there is no *significant* release below the lower end of the range, pH 5.0). The parties hotly
24 dispute the significance of: 1) the applicants' reliance on the Kurasawa testing during patent
25 prosecution; and 2) the disclosure in columns 9 and 10 of the '755 Patent. Beyond the fact that
26 both describe testing that was conducted over a longer period of time than Takeda asserts is
27 appropriate for determining whether the release limitation is satisfied, suggesting that the two-
28 hour limitation proposed by Takeda is incorrect, the Court finds that neither the prosecution

1 history nor the passage in the specification offers significant guidance as to the construction of the
2 release term.

3 On one hand, the Kurasawa testing revealed a dissolution rate of less than 5% dissolution
4 after 2 hours and thus, the embodiment of the invention tested by Kurasawa would not have
5 satisfied the “significant and rapid” requirement that Takeda asks the Court to read into the
6 release term.¹⁷ On the other hand, the single example describing testing in the specification,
7 found in columns 9 and 10, arguably supports Takeda’s position that claim 1 allows some release
8 below the claimed pH ranges. That passage states as follows:

9 It is desirable that the coating material is used alone or, if necessary,
10 in combination so that the polymer is dissolved, preferably at a pH
11 of 6.0 or above, more preferably at a pH of 6.5 or above, and further
12 more preferably at a pH of 6.75 or above. . . . The rate of elution of
13 active ingredient from the active-ingredient release-controlled
14 tablet, granule or fine granule thus obtained is desirably 10% or less
15 for 5 hours in a solution of pH 6.0, and 5% or less for one hour and
16 60% or more for 8 hours in a solution of pH 6.8.

17 ‘755 Patent, col. 9, l. 65 - col. 10, l. 17. Neither of the examples, however, addresses whether (or
18 when) the release described in them falls within the range set forth in the release term. Moreover,
19 even if Takeda is correct that the passage in the specification describes an embodiment that is
20 excluded under the Court’s current construction of the release term, this does not justify
21 modifying the construction because “the unambiguous language of the . . . claim controls over
22 any contradictory language in the written description.” *Elekta*, 214 F.3d at 1308. Finally, to the
23 extent that the Court finds that the claims themselves are unambiguous, reliance on extrinsic
24 evidence, such as the USP, is not a proper basis for varying the meaning of the term. *See*
25 *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) (“In most situations,
26 an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In
27 such circumstances, it is improper to rely on extrinsic evidence.”).

28 ¹⁷The Court notes that the Kurasawa testing involved the high pH granule rather than the low pH granule that is the subject of the release term. Nonetheless, at claim construction Takeda argued that the Kurasawa testing would have offered guidance to a person of ordinary skill in the art as to how to measure whether the release term was satisfied.

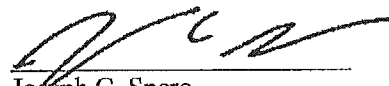
1 For these reasons, the Court concludes that it is not appropriate to revise its construction
2 of the release term to insert qualifying language requiring that release must be rapid and
3 significant. Rather, the Court finds that a product falls outside of the ambit of claim 1 if there is
4 any measurable release of the API from the low pH granule below the range specified in the
5 release term. Because Takeda's own testing shows measurable release of the low pH capsule of
6 TWi's ANDA products below a level of pH 5.0, the Court finds as a matter of law that those
7 products do not infringe the asserted claims of the '755 Patent.¹⁸

8 **IV. CONCLUSION**

9 For the reasons stated above, Takeda's Motion for Summary Judgment is GRANTED.
10 TWi's Motion is GRANTED in part and DENIED in part.

11 IT IS SO ORDERED.

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13 Dated: April 8, 2013

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16 Joseph C. Spero
17 United States Magistrate Judge
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27 ¹⁸ Because the Court finds that TWi is entitled to summary judgment of non-infringement as to
28 the '755 Patent, it need not reach TWi's argument that the Advantar test results are not relevant
because they were run after the ANDA product batch had already expired.